

EXHIBIT B

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA ex rel.
[SEALED],

Plaintiff-Relator,

v.

[SEALED],

Defendants.

Civ. Action No. 19-cv-2553

FILED UNDER SEAL
DO NOT PLACE ON PACER

(Plaintiff-Relator demands a trial by jury on
all counts)

**RELATOR'S SEALED SECOND AMENDED QUI TAM COMPLAINT
FILED UNDER SEAL PURSUANT TO 28 U.S.C. § 3730(b)(2)**

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FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA ex rel.
ELLSWORTH ASSOCIATES, LLP,

Plaintiff-Relator,

v.

CVS HEALTH CORPORATION,
SILVERSCRIPT INSURANCE COMPANY,
LLC, CVS CAREMARK CORPORATION,
and CVS PHARMACY, INC.,

Defendants.

Civ. Action No. 19-cv-2553

FILED UNDER SEAL

Pursuant to 31 U.S.C. § 3730(b)(2)

(Plaintiff-Relator demands a trial by jury on
all counts)

**SECOND AMENDED COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS
UNDER 31 U.S.C. § 3729, ET SEQ.**

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SECOND AMENDED COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS
UNDER 31 U.S.C. § 3729, ET SEQ.

On behalf of the United States of America (“United States”), Plaintiff-Relator Ellsworth Associates, LLP (“Relator”) hereby files this Second Amended Complaint against Defendants CVS Health Corporation (“CVS Health”), SilverScript Insurance Company, LLC (“SilverScript”), CVS Caremark Corporation (“CVS Caremark”), and CVS Pharmacy, Inc., (collectively herein “the CVS Defendants,” “CVS,” or “CVS Health”), pursuant to the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (“FCA”). Relator brings this action on behalf of the United States to recover damages and civil penalties under the FCA, arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used, or presented by Defendants and/or their agents, predecessors, successors, and employees in violation of the FCA, as amended.

I. INTRODUCTION

1. CVS Health has devised an intentionally fraudulent Single Source Generic/Do Not Substitute scheme (hereinafter the “SSG/DNS Scheme”) to prevent Medicare Part D beneficiaries from accessing less costly, equivalent versions of numerous generic prescription drugs in favor of much costlier, multi-source brand-name drugs. In doing so, CVS Health has ensured astonishing profits for itself while passing the increased costs onto taxpayers and Part D beneficiaries. Sadly, the SSG/DNS Scheme has disproportionately affected many elderly, end stage renal disease (“ESRD”), and disabled SilverScript Part D beneficiaries who, given their cost sensitivities, have been forced to forgo critical treatment due to the higher cost shares resulting from the blocking of less expensive generic drugs.

2. Medicare Part D relies on fair competition in private market negotiations between Part D plans, PBMs, pharmacies and drug makers to ensure that the benefits offered provide quality

drugs at affordable prices. Unlike Medicare Parts A and B, which are administered by Medicare itself, the Medicare Part D prescription drug benefit was designed to be offered only by the private companies which contract with the government to provide competitive prescription benefits to attract beneficiaries.

3. Here, the conduct of CVS Health and its subsidiaries cheated beneficiaries and taxpayers by selling off access to Part D formularies to the SSG/DNS Drug Makers in exchange for blocking access to less costly generic drugs. In doing so, the CVS Health entities betrayed the marketing promise made to prospective members that SilverScript could be trusted to act only on their behalf “every day, in every way.”

4. In reality, behind closed doors CVS Health and its subsidiaries had sold off SilverScript Part D formulary access to the SSG/DNS Drug Makers who were intent on obstructing competition for their blockbuster drugs.

5. The fraudulent conduct alleged herein has been implemented through the SSG/DNS Scheme and started at least as early as June 22, 2015 and continues up through today. The SSG/DNS Scheme has involved, in relevant part, at least the following fifteen drugs (and their manufacturers, collectively the “Drug Makers”): Copaxone (Teva), Exelon (Novartis), Voltaren Gel (Endo), Invega (Janssen), Asacol HD (Allergan), Xopenex HFA (Sunovion), Renvela Packets (Sanofi), Renvela Tablets (Sanofi), Istalol (Bausch & Lomb), Harvoni (Gilead), Epclusa (Gilead), Ventolin HFA (GSK), Canasa Rectal Suppository (Allergan), Advair Diskus (GSK), and Suboxone Sublingual Film (Indivior). Collectively herein these fifteen (15) drugs are referred to as the “SSG/DNS Drugs.”

6. The secret SSG/DNS deals cut by the CVS Health entities became key to facilitating the Drug Makers’ evergreening, pay-for-delay, product hopping, sham patent litigation,

sham Citizen's Petitions, authorized generic and other schemes (used in combination or separately) to block generic competition. As such, the CVS Health entities' SSG/DNS Scheme has aided and abetted the Drug Makers competing not solely on the basis of innovation, but rather on their ability to obstruct access to generic competition.

7. The complicity among CVS Health's Part D Plan Sponsor (SilverScript), its pharmacy benefit manager (CVS Caremark), and pharmacies (CVS Pharmacies) has created a veritable playground of opportunities to hold off generic competition, allowing the Drug Makers free reign to block beneficiary access to less costly generic drugs, frequently authorized generics. This obstruction would otherwise have been impossible if the CVS Health entities had not colluded together, particularly given their different competing interests, which were supposedly firewalled off from each other because of a 2007 agreement with the Federal Trade Commission ("FTC") at the time of the merger between CVS and Caremark.

8. Normally, arm's length competitive interactions between PDPs, PBMs and pharmacies would have served as a system of checks and balances to ensure that consumers had access to affordable medications. But with all its wholly-owned subsidiaries conspiring together, CVS Health has been able to achieve an "enterprise-wide benefit" from the anticompetitive deals with the Drug Makers that has padded its bottom line, but has harmed taxpayers as well as elderly, ESRD and disabled Part D beneficiaries.

9. The Scheme required collusion between the supposedly firewalled CVS Health entities. Under the terms of secret rebate agreements between the SSG Drug Makers and CVS Caremark, SilverScript was required to block substitution on its formularies of generic drugs in favor of the much more expensive brand-name SSG/DNS Drugs.

10. Most disturbing is SilverScript required its call center Customer Care

Representatives (“CCRs”) to provide intentionally misleading information to SilverScript beneficiaries about access to less costly generic drugs and, more troublingly, provide outright falsehoods that the brand-name SSG/DNS Drugs would be less costly for the beneficiary than the generic. These CCR representations were not only aimed at discouraging SilverScript beneficiaries into abandoning coverage determination requests to change to less costly drugs, they were palpably false.

11. Along the way, SilverScript’s CCRs became unsuspecting accomplices in the SSG/DNS Scheme, frequently themselves expressing confusion disappointment during beneficiary calls because (even though they could see on their computer screens that less costly generic alternatives should be available) they were unable to offer elderly, ESRD and disabled beneficiaries access to these less costly medications, which were blocked on the SilverScript formulary.

12. Even if beneficiaries were occasionally able to fight through the misinformation they received from SilverScript, CVS Health ultimately has ensured the much costlier brand-name drug was still dispensed by requiring the CVS Pharmacies to block Part D claims for the less costly generic versions.

13. At its core, the SSG/DNS Scheme has involved a calculated and widespread campaign of misinformation, deception, and outright lies to SilverScript beneficiaries. In doing so, CVS Health and its subsidiaries have denied Part D beneficiaries the opportunity to obtain less costly generic drugs by withholding information about generic options, lying to those who seek out pricing information on generic options, and denying formulary exceptions to those who are occasionally able to get through the web of lies.

14. If that were not enough, realizing there was even more profit to be made if

beneficiaries' access to less costly options were eliminated entirely, the rebate deals that CVS Caremark had struck required the blanket denial of all formulary exceptions for certain of the SSG/DNS Scheme's most expensive drugs, specifically Gilead's Harvoni and Epclusa, driving elderly, ESRD and disabled beneficiaries into the Catastrophic Coverage Stage of their Part D benefits, where they faced substantial additional costs.

15. Not just that, under the rebate agreements CVS Caremark had entered into with Gilead and GSK, the CVS Pharmacies were required to stop stocking not just the generic versions for Gilead's Harvoni and Epclusa but also GSK's Advair Diskus and Ventolin HFA, violating CMS's uniformity of benefits requirement.

16. The sharing of sensitive competitive information across the CVS Health subsidiaries has ensured that the fraudulent SSG/DNS Scheme could be successful. Even though the fraudulent scheme violates Federal anticompetition laws as well as State laws requiring pharmacies to substitute generic medications for the costlier brand-name versions, because CVS Health owned (and therefore controlled) the SilverScript PDP, the CVS Caremark PBM, and the CVS Pharmacies, any potential competitive discord between its goal of dispensing more expensive brand-name SSG/DNS Drugs and what Federal and State laws required would simply be ignored. Because of what they cynically termed internally as the "enterprise-wide" benefit to the parent CVS Health, they would simply flout any obligation to provide truthful, non-deceptive information to beneficiaries and/or to dispense the less costly generics.

17. CVS Health's actions are particularly brazen because it had in 2012 entered into a Settlement Agreement and Consent Order with the FTC, under which it agreed for a period of twenty (20) years that it would not make deceptive claims, directly or indirectly, "expressly or by

implication, [in connection with] *the price or cost of Medicare Part D prescription drugs....*”¹

18. This fraudulent and deceptive conduct has had the blessing of the CVS Health Executive Committee, the committee of senior executives who were charged with overseeing activities across the parent corporation and its subsidiaries. Even though many in the organization (including the Relator) had raised concerns about the ethics and legality of the Scheme, and even though its Code of Conduct required these executives to “Do the Right Thing,” the Executive Committee ignored these admonitions and approved it nonetheless because the financial benefit to the company was simply too tempting to pass up.

19. The unfortunate casualties have been SilverScript elderly, ESRD and disabled beneficiaries. In call after Customer Care call from these beneficiaries seeking less costly options, what comes through is that the increased cost for many would involve delaying or rationing needed lifesaving drugs, and for others the drugs would simply be unaffordable. What also is clear is that the Executive Committee calibrated that the Scheme would be worth the risk because of their conclusion that only a few of the SilverScript beneficiaries would complain and, if they did call in to complain, would simply give up after being bounced from CCR to CCR. Clearly, for CVS Health doing the “Right Thing” was only window dressing.

20. But, as one caller, a 78-year-old retired nurse from Massachusetts, responded when told by the CCR she could only get the brand Advair Diskus she needed to treat her asthma instead of the 70% less costly generic: “It sounds like SilverScript just doesn’t want to change because it’s to their benefit.... I’m not feeling that they’re thinking of the consumer.... It shouldn’t be that way.”

21. Beyond the ethical and moral implications of deceiving SilverScript’s vulnerable

¹ FTC Agreement Containing Consent Order, *In the Matter of CVS Caremark Corporation*, File No: 112-3210, at Section VIII, p. 8 (emphasis added).

elderly, ESRD and disabled Part D beneficiaries, CVS Health's conduct also has violated numerous laws. Fundamentally, the SSG/DNS Scheme violates:

- a) The FTC Consent Order that it would not, directly or indirectly, make deceptive claims about the price or cost of Medicare Part D prescription drugs, and is thereby liable for civil monetary penalties of up to \$10,000 per violation, pursuant to Section 5(l) of the FTC Act.
- b) Its obligation under the Federal antitrust laws not to engage in deceptive business practices that unreasonably deprive consumers of the benefits of competition.
- c) Its obligation under the Federal antitrust laws not to share competitively sensitive information between its firewalled subsidiaries, which conduct was aimed at driving up prices for the SSG/DNS Drugs, thereby harming elderly, ESRD and disabled SilverScript beneficiaries.
- d) Knowingly submitting or causing to be submitted hundreds of thousands of inaccurate, incomplete and untruthful prescription drug event ("PDE") records for the purpose of unlawfully obtaining reimbursement payments higher than those authorized by law.
- e) Annually falsely attesting that, as a condition of participation, it had complied with Federal laws and regulations designed to prevent or ameliorate fraud and deceptive conduct, including compliance with the False Claims Act.
- f) Submitting (or causing the submission of) what it knew to be false claims for the SSG/DNS Drugs furnished to SilverScript beneficiaries.
- g) Submitting (or causing the submission of) what it knew to be materially false records and statements in support of false claims presented to the Government.

22. In furtherance of the illegal SSG/DNS Scheme, CVS Health has engaged in widespread fraudulent and deceptive conduct made possible by its derogation of:

- a) Its obligations to have in place a robust and effective compliance program.
- b) Its promise as spelled out in its Code of Conduct that it would operate fairly and ethically.
- c) Its obligation that it be honest and forthright in all its dealings with both the Government and Part D beneficiaries.
- d) Its obligation to fully and fairly adjudicate grievances and coverage determinations.
- e) Its duty to disclose differential pricing for less costly generic drugs to Part D beneficiaries.
- f) Its obligation to provide nondiscriminatory, uniform benefits under the Medicare Part D program.
- g) Its promise to submit truthful, accurate and complete records in support of Medicare Part D claims.
- h) Its agreement to pay only “valid” claims – *i.e.*, claims valid under State laws requiring mandatory generic substitution.

23. CVS Health has made numerous false and misleading public statements and promises about its commitment to compliance and ensuring economical access to medication through competition. But these statements – like the falsehoods made to numerous Part D beneficiaries – were intended to help Defendants avoid detection and to conceal their fraudulent and deceptive conduct.

24. As a direct result of Defendants’ fraudulent, improper and illegal practices, the United States has continued to:

- a) Pay false or fraudulent claims related to invalid Part D prescriptions that would not have been paid but for CVS Health's intentional, illegal, improper, and reckless business practices.
- b) Pay increased subsidies to SilverScript through direct advance monthly payments; reinsurance subsidies; low-income cost-sharing subsidies (or grants for low-income Part D individuals received in lieu of low-income subsidies); risk-sharing arrangements; and/or year-end retroactive adjustments and reconciliations.
- c) Re-entered into contracts with CVS Health as a provider of Part D services through SilverScript, as a PBM through CVS Caremark, or contracted network pharmacies through the CVS Pharmacies, based on false annual attestations to the accuracy and truthfulness of its PDE data² and that they had complied "with . . . Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law [and] the False Claims Act (31 USC §§ 3729 et seq.)."³

25. The aforementioned conduct is ongoing.

26. The causes of action alleged herein are timely brought because, among other things, of efforts by Defendants to conceal from the United States its wrongdoing in connection with the allegations made herein.

II. PERFECTION OF FILING AND STANDING

27. This Second Amended Complaint was properly filed in camera and under seal, as required by the FCA, and shall remain under seal for at least sixty days as required by said

² 42 C.F.R. § 423.505(k).

³ 42 C.F.R. § 423.

provisions.

28. In advance of the filing of the Second Amended Complaint, Plaintiff properly served a copy of the Second Amended Complaint and written disclosure of substantially all material evidence and information supporting these allegations upon the United States.

29. Relator is not aware of any “public disclosure,” as that term is used in the FCA, of the allegations forming the core elements of the Counts against CVS Health.

30. In the event there is found to be any such public disclosure, Relator is an “original source,” as that term is used in the FCA, of the allegations or transactions forming the core elements of the cause(s) of action against CVS Health.

31. In particular, Relator has direct and independent knowledge of the information on which the allegations are based, and voluntarily provided that information to the Federal Government before filing this action. Furthermore, and consistent with the meaning of “original source” under the FCA, Relator either “voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based” prior to any public disclosure under subsection (e)(4)(A), or has “knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions and voluntarily provided the information to the Government before filing” this action.

III. PARTIES

A. Relator

32. Relator ELLSWORTH ASSOCIATES, LLP (hereinafter “Relator”), a Delaware limited liability partnership, brings this action on behalf of itself and the United States of America. The registered office of Relator is located at 1925 Lovering Avenue, Wilmington, Delaware 19806, and the name of the registered agent at such address is The First State Registered Agent Company.

33. Pursuant to Section 15-201(a) of the Delaware Revised Uniform Partnership Act, Relator is not distinct from its partners. At least one of its partners, Alexandra Miller, who by virtue of employment with CVS Health, at all times material hereto has had firsthand, personal knowledge of the false claims, statements, and concealments alleged herein.

34. Ms. Miller was employed by CVS Health for 19 years, eventually being promoted to a senior executive position. She has extensive personal knowledge and experience regarding the SSG/DNS Scheme alleged herein, including personal contact with the CVS Health employees and executives who have committed violations of law alleged herein.

35. When Ms. Miller complained to a supervisor that the SSG/DNS Scheme was unethical and violated the company Code of Conduct, the supervisor said that senior management on the Executive Committee (as well as the Chief of Compliance for CVS Health, Medicare, Patrick Jeswald) had already decided that the upside benefit to the “enterprise” was much greater than the risk that its wrongdoing would be detected by the Government. As such, Relator had no recourse internally to redress these concerns.

36. Relator thus has direct knowledge of the conduct alleged in this Second Amended Complaint and conducted an independent investigation to uncover false claims submitted to the United States. Accordingly, Relator is an “original source” of the non-public information alleged in this Second Amended Complaint within the meaning of the FCA.

B. Defendants CVS Health, SilverScript, CVS Caremark, and CVS Pharmacies

37. CVS HEALTH CORPORATION, formerly known as CVS Caremark Corporation, (hereinafter “CVS Health”) is incorporated under the laws of the state of Delaware, and headquartered at One CVS Drive, Woonsocket, Rhode Island 02895.

38. CVS Health has reported to the public that since at least 2007 it has been the largest provider of prescription and related healthcare services in the United States. During the year ended

December 31, 2018, the Company's PBM filled or managed approximately 1.9 billion prescriptions on a 30-day equivalent basis. CVS Health operates three business segments: Pharmacy Services, Retail/Long-term Care, and Health Care Benefits:

- **The Pharmacy Services** segment provides a range of pharmacy benefit management ("PBM") plans, including plan design offerings and administration, formulary management, retail pharmacy network management services, mail order pharmacy, specialty pharmacy and infusion services, Medicare Part D services, clinical services, disease management services and medical spend management. The Pharmacy Services segment's clients include Medicare Part D prescription drug plans ("Part D plans" or "PDPs") throughout the United States. In addition, through SilverScript, CVS Health is a national provider of drug benefits to eligible beneficiaries under the Medicare Part D prescription drug program. The Pharmacy Services segment operates retail specialty pharmacy stores, specialty mail order pharmacies, mail order dispensing pharmacies, compounding pharmacies and branches for infusion and enteral nutrition services.
- **The Retail/Long-term Care ("LTC")** segment sells prescription drugs and general merchandise. As of December 31, 2018, the Retail/LTC segment operated more than 9,900 retail locations. During the year ended December 31, 2018, the Retail/LTC segment filled approximately 1.3 billion prescriptions.
- **The Health Care Benefits** segment is one of the nation's largest diversified health care benefits providers, serving an estimated 38 million people as of December 31, 2018. The Health Care Benefits segment offers a range of traditional, voluntary and consumer-directed health insurance products and related services, including

Medicare Advantage and Medicare Supplement plans, and PDPs.

39. All prescriptions managed by CVS Health, whether filled at one of its own mail service pharmacies, its specialty pharmacies, or through one of its retail pharmacies, are uniformly and systematically analyzed, processed and documented by CVS Health's nationwide proprietary prescription management systems.

40. According to CVS Health's own financial reports, these uniform computerized prescription management systems assist staff and network pharmacists in the processing of prescriptions by automating tests for various items, including plan eligibility, early refills, duplicate dispensing, appropriateness of dosage-drug interactions or allergies, over-utilization and potential fraud issues.

41. SILVERSCRIPT INSURANCE COMPANY ("SilverScript") is a Tennessee corporation with its principal place of business located at 300 Montvue Rd., Knoxville, Tennessee. SilverScript is a corporate affiliate of CVS Health. SilverScript is the largest PDP in the United States and has the largest number of beneficiaries of any Medicare PDP in the country who are eligible for the low-income subsidy whereby the Government subsidizes most of the Part D premium, deductibles and cost sharing.

42. CVS Health subsidiary CVS CAREMARK CORPORATION ("CVS Caremark") (formerly "Caremark Rx") is one of largest the PBMs in the United States. CVS Caremark is headquartered in Woonsocket, Rhode Island. Through SilverScript, it provides PBM services (including formulary development and establishing and maintaining pharmacy networks) as well as for PDP Sponsors throughout the country.

43. CVS PHARMACY, INC. ("CVS Pharmacy") is a Rhode Island corporation whose principal place of business is at the same location as CVS Health. CVS Pharmacy is owned and

controlled by CVS Health. As alleged herein, CVS Pharmacy, Inc. includes its nearly 9,900 retail pharmacies located throughout the U.S., CVS Caremark Mail Service Pharmacy, Inc., CVS Specialty Pharmacy, Inc., Navarro Discount Pharmacies, Inc., and Longs Drugs, Inc. These entities shall collectively be referred herein as the “CVS Pharmacies.”

44. In short, CVS Health, through its subsidiaries, operates the Medicare PDP SilverScript, the PBM CVS Caremark, as well as retail, mail order, specialty mail order and retail pharmacies, the CVS Pharmacies, all of which conduct business throughout the United States and/or its legal territories, and in this District.

IV. JURISDICTION AND VENUE

45. Pursuant to 28 U.S.C. § 1331, this District Court has original jurisdiction over the subject matter of this civil action since it arises under the laws of the United States—in particular, the FCA, 31 U.S.C. §§ 3729 *et seq.* (“FCA”). In addition, the FCA specifically confers jurisdiction upon the United States District Court.⁴

46. This District Court has personal jurisdiction over CVS Health pursuant to 31 U.S.C. § 3732(a) because the FCA authorizes nationwide service of process and CVS Health has sufficient minimum contacts with the United States of America. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a). CVS Health transacts business within this District, and acts proscribed by 31 U.S.C. § 3729, *et seq.* occurred in this district.

47. CVS Health’s operations within this District include numerous retail stores (operating fifty-eight CVS retail pharmacies in Philadelphia alone), along with offices in Blue Bell, Pennsylvania, and a substantial presence for its Medicare Part D Program SilverScript in this District, including some 96,419 enrolled SilverScript beneficiaries in Pennsylvania (many of

⁴ 31 U.S.C. § 3732(b).

whom reside in this District). Moreover, at all times material hereto, the Philadelphia Regional Office for CMS has had direct oversight for the SilverScript plan.

V. NATURE OF ACTION

A. The False Claims Act

48. The False Claims Act prohibits:

- “knowingly” presenting or causing to be presented to the United States any false or fraudulent claim for payment or approval, 31 U.S.C § 3729(a)(1)(A);
- “knowingly” making, using, or causing to be used or made, a false record or statement material to a false or fraudulent claim, *id.* § 3729(a)(1)(B); and
- conspiring to commit a violation of the FCA, *id.* § 3729(a)(1)(C).

49. As defined under 31 U.S.C. § 3729(b), “knowing” and “knowingly” mean that a person: (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information.

50. Under 31 U.S.C. § 3729(c), a “claim” includes “any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.”⁵ Under this language, Medicare claims submitted to Federal agencies are claims presented to the Federal Government and therefore give rise to liability under the FCA.

51. Under the FCA, “the term ‘material’ means having a natural tendency to influence,

⁵ 31 U.S.C. § 3729(c).

or be capable of influencing, the payment or receipt of money or property.”⁶

52. The FCA enforces certain principles that apply when one deals with the Federal Government. These include the fact that *caveat emptor* is replaced by a duty to “turn square corners” and be honest and forthright with the Government, and to deliver goods and services precisely according to the specifications mandated.⁷ This principle is reflected in the fact that the FCA mandates civil monetary penalties of not less than eleven thousand one hundred eighty-one (\$11,181) or more than twenty-two thousand three hundred sixty-three dollars (\$22,363) per claim.⁸

53. In addition, when the misconduct results in the Government paying more than the value it received, then that difference is subject to mandatory trebling. FCA damages are the

⁶ 31 U.S.C. § 3729(a)(D).

⁷ *Caveat emptor* does not apply when dealing with the Government. As stated long ago by Justice Holmes, “[m]en must turn square corners when they deal with the government.” *Rock Island, Arkansas & Louisiana R.R. v. United States*, 254 U.S. 141, 143, 41 S.Ct. 55, 65 L.Ed. 188 (1920); see also *Fed. Crop Ins. Corp. v. Merrill*, 332 U.S. 380, 385 (1947) (setting out the fact that “[m]en must turn square corners when they deal with the Government,” does not reflect a callous outlook. It merely expresses the duty of all courts to observe the conditions defined by Congress for charging the public treasury”). Important here, the principle is also widely applied in FCA actions. See, e.g., *U.S. v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008); *U.S. ex rel. Compton v. Midwest Specialties, Inc.*, 142 F.3d 296, 302-05 & n.4 (6th Cir. 1998) (setting out that “parties that contract with the government are held to the letter of the contract – irrespective of whether the contract terms appear onerous from an ex post perspective, or whether the contract's purpose could be effectuated in some other way” and thus “the ‘square-corners’ rule applies fully in the False Claims Act context”), following *United States v. Aerodex, Inc.*, 469 F.2d 1003, 1007 (5th Cir. 1972) (noting that “[t]he mere fact that the item supplied under contract is as good as the one contracted for does not relieve defendants of liability”)(emphasis added); *U.S. v. Rivera*, 55 F.3d 703,709 (1st Cir. 1995) (setting out that “[b]y attaching liability to the claim or demand for payment [under (a)(1), the [FCA] encourages contractor [sic] to ‘turn square corners when they deal with the government’”), quoted and followed by *Machado v. Sanjurjo*, 559 F.Supp.2d 167, 174 (D. Puerto Rico 2008); *United States v. Bourseau*, No. 03-cv-907, 2006WL2961105, * 1 & n.1 (S.D. Cal. 2006).

⁸ 31 U.S.C. § 3729(a)(1).

difference in value between what the Government paid and what it received.

54. According to Senator Charles Grassley, “when citizens contract with the government, they contract with the taxpayers. When they cheat the government, they cheat the taxpayers. Why does this matter so much? It matters because fraud on the government costs much more than money ‘[F]raud erodes public confidence in the Government’s ability to efficiently and effectively manage its programs.’”⁹

B. Antitrust Remedies Under the Clayton Act, Section 4A

55. The antitrust laws prohibit business practices that unreasonably deprive consumers of the benefits of competition. In the case of access to affordable medications, no competition means higher prices, often resulting in inferior patient adherence to frequently lifesaving medicines.

56. The three major antitrust laws are:

- The Sherman Antitrust Act prohibits all contracts, schemes and conspiracies that unreasonably restrain interstate and foreign trade. The law also prohibits monopolies.
- The Clayton Act prohibits mergers or acquisitions that materially diminish competition.
- The final piece of legislation in the government’s antitrust arsenal is the Federal Trade Commission Act, which prohibits unfair methods of competition.

57. Section 4A of the Clayton Act allows the government to recover treble damages for antitrust violations when the government itself is the victim.

⁹ Senator Charles Grassley, *Grassley: False Claims Act is Our Most Important Tool to Fight Fraud against Taxpayers*, Statement for the Record by Senator Chuck Grassley of Iowa, Chairman, Senate Judiciary Committee at a House Judiciary Subcommittee on the Constitution and Civil Justice Hearing on “Oversight of the False Claims Act,” (April 28, 2016), <https://www.grassley.senate.gov/news/news-releases/grassley-false-claims-act-our-most-important-tool-fight-fraud-against-taxpayers>.

58. According to then Assistant Attorney General Makan Delrahim, “Section 4A of the Clayton Act is a powerful enforcement tool that empowers the United States to obtain treble damages for anticompetitive conduct when the government is itself the victim.”¹⁰

59. Indeed, in 1955, Congress amended the Clayton Act to add Section 4A to ensure that the government fell within the statute’s scope and could bring claims to recover damages where it was the victim of an antitrust violation. Originally, Section 4A allowed the government to recover only single damages; however, in 1990, Congress further amended the Clayton Act to allow the government to seek treble damages pursuant to that provision.¹¹

C. Overview of Medicare Part D

1. Medicare Part D Relies on a Competitive Marketplace Where Plans Negotiate Pricing that Provides Access to Affordable, Lifesaving Drugs

60. Medicare is a federally funded and administered health insurance program for certain groups, primarily elderly, ESRD and disabled persons. The Department of Health and Human Services (“HHS”) administers the Medicare program through CMS. Medicare Part D, one of four parts of Medicare, is the voluntary prescription drug benefit program established in 2003 by the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. 108-173, 117 Stat. 2066. It became effective January 1, 2006.¹²

61. Medicare Part D is based on a private market model in which CMS contracts with

¹⁰ Makan Delrahim, “November Rain”: *Antitrust Enforcement on Behalf of American Consumers and Taxpayers* (Nov. 15, 2018) (Remarks as Prepared for Delivery at the American Bar Association Antitrust Section Fall Forum), available at <https://www.justice.gov/opa/speech/assistant-attorneygeneral-makan-delrahim-remarks-american-bar-association-antitrust>.

¹¹ *Id.*

¹² 42 U.S.C. § 1395w-101(a)(2).

private entities, known as “Sponsors” to administer prescription drug plans or “PDPs.”¹³

62. For the Medicare Part D private model to operate successfully, according to the HHS Office of Health Policy, “[t]he United States relies on the interactions of private entities – drug manufacturers, health plans and pharmaceutical benefit managers (PBMs) – to achieve value by negotiating prices, operating formularies and implementing other benefit management strategies.”¹⁴

63. Policymakers envisioned the Part D program would rely on private plan sponsors that bear insurance risk competing in the marketplace to provide attractive benefit packages and drug prices that are fairly negotiated in order to make these often lifesaving medications more affordable.

64. Plan sponsors that collude with others to increase prices for Part D drugs not only rob taxpayers, they cheat beneficiaries who often are forced to ration or abandon their medications altogether. This is particularly insidious when this conduct increases prices for expensive drugs that force their Part D coverage into the Catastrophic Coverage Stage where beneficiaries face substantial additional costs.

65. According to the Kaiser Family Foundation, between 2010 and 2019, the number of Part D beneficiaries with out-of-pocket spending above the Catastrophic Coverage threshold had tripled, and by 2019 nearly 1.5 million Medicare Part D enrollees had out-of-pocket spending

¹³ *Id.* § 423.265.

¹⁴ HHS Assistant Secretary of Planning and Evaluation, *Medicare Part D: Competition and Generic Drug Prices* (Jan. 19, 2021), 2007-2018, at 2; *see also* Douglas Holtz-Eakin, Robert Book, *Competition and the Medicare Part D Program* (Sep. 11, 2013), available at <https://www.americanactionforum.org/research/competition-and-the-medicare-part-d-program/>

above the threshold.¹⁵

2. Medicare Part D Bids from PDPs Rely on Accurate, Complete, and Truthful PDE Records Submitted to CMS

66. Instead of setting payments to Part D plans, Medicare's payments are based on bids submitted by private plan sponsors that reflect their average cost (including administrative expenses and an operating margin) of providing a basic outpatient drug benefit to an enrollee of average health.

67. Under Part D, a PDP Sponsor submits a bid in the year prior to the calendar year in which benefits will actually be delivered, which contains a per member per month cost estimate for providing benefits to an average Medicare beneficiary in a particular geographic region.¹⁶

68. From the bids, CMS calculates nationwide and regional benchmarks, which represent the average per member, per month cost.¹⁷ If the Sponsor's bid exceeds the benchmark, the enrolled beneficiary must pay the difference as part of a monthly premium.¹⁸ CMS then provides each PDP Sponsor with advance monthly payments equal to the Sponsor's standardized bid, risk-adjusted for health status, minus other amounts that the Sponsor is expected to receive from other sources.¹⁹

¹⁵ Juliette Cubanski, Tricia Neuman, and Anthony Damico, *Millions of Medicare Part D Enrollees Have Had Out-of-Pocket Drug Spending Above the Catastrophic Threshold Over Time*, Kaiser Family Foundation (July 23, 2021), available at <https://www.kff.org/medicare/issue-brief/millions-of-medicare-part-d-enrollees-have-had-out-of-pocket-drug-spending-above-the-catastrophic-threshold-over-time/>

¹⁶ *Id.* at §§ 423.265, 423.272.

¹⁷ *Id.* at § 423.279.

¹⁸ *Id.* at § 423.286.

¹⁹ 42 C.F.R. § 423.293.

69. When a PDP network pharmacy dispenses a drug to a Medicare beneficiary, it submits an electronic claim to the beneficiary's PDP and receives reimbursement from the Sponsor for the costs not paid by the beneficiary. The Sponsor (or its PBM) then submits a Prescription Drug Event ("PDE") record to CMS that reflects a drug has been purchased and dispensed. The PDE record includes the amount paid to the pharmacy by the beneficiary. The PDE is an electronically created document that includes multiple transactional and calculated fields about a specific drug dispensed.

70. CMS uses this information in the PDE at the end of the payment year to reconcile its advance payments to the Sponsor with actual costs the PDP Sponsor incurred.²⁰ If a PDP Sponsor's actual costs exceed the estimated costs, the Sponsor may be able to recoup some of its losses through a risk sharing agreement with CMS.²¹ If a Sponsor's estimated costs exceed its actual costs by a specified amount, payments to the PDP Sponsor for the year are reduced and the Sponsor will have to pay back some its estimated payments.²²

71. PDP Sponsors subcontract with multiple entities to provide drugs to the Medicare Part D beneficiaries enrolled in their PDPs, including subcontracts with pharmacy benefits managers or "PBMs," which administer at minimum the PDP's formulary and pharmacy benefit and arrange for various pharmacies to participate in the plan's pharmacy network so members have "access to their needed drugs. As a condition for receiving its monthly payment from CMS, a PDP Sponsor must certify as to the accuracy, completeness, and truthfulness of all data related to the

²⁰ Instructions: Requirements for Submitting Prescription Drug Event Data ("CMS Instructions").

²¹ *Id.* at 9–10.

²² *Id.*

payment, which may include enrollment information, claims data, bid submission data, and any other data specified by CMS.”²³

72. If the claims data has been generated by a subcontractor of a PDP Sponsor, such as a PBM, that entity must “similarly certify” that the claims data it has generated is accurate, complete and truthful, and must acknowledge that it will be used to obtain Federal reimbursement.²⁴

73. PDP Sponsors must also certify in their contracts with CMS that they agree to comply with all Federal laws and regulations designed to prevent fraud, waste, and abuse, including the False Claims Act.²⁵ CMS regulations require that all subcontracts between PDP Sponsors and downstream entities, including PBMs and pharmacies, require compliance by those entities with all applicable Federal laws, regulations, and CMS instructions.²⁶

74. Part D beneficiaries’ coverage varies by the benefit design and cost of drug usage over the course of a plan year:

a) Deductible: As with most insurance plans, beneficiaries do not receive any benefits under Medicare Part D until their out-of-pocket costs for prescription drugs meets a modest deductible amount (up to \$415 for 2019). LIS 1, 2, and 3 beneficiaries do not have a deductible. LIS 4 beneficiaries do have a reduced deductible.

b) Initial Coverage Limits (“ICL”): Once a beneficiary meets his or her deductible,

²³ 42 C.F.R. § 423.505(k)(1).

²⁴ *Id.* at § 452.505(k)(3).

²⁵ *Id.* at § 423.505(h)(1).

²⁶ *Id.* at § 423.505(i)(4)(iv).

they receive prescription drug benefits up to an annual cap (\$3,820 for 2019).

- c) Coverage Gap (the “Donut Hole”): After the beneficiary reaches the cap of the initial coverage, they fall into a coverage gap until their total out-of-pocket costs reach a threshold for catastrophic coverage (\$5,100 for 2019). In the coverage gap, a beneficiary pays more for a brand-name drug that is more expensive than its generic alternative. The coverage gap discount program does not apply to LIS beneficiaries.
- d) Catastrophic Coverage: After the beneficiary meets the threshold amount, they are again entitled to prescription drug benefits under a reinsurance scheme in which the United States Treasury pays 80% of drug costs, the PDP Sponsor pays 15% and the beneficiary pays 5%.

75. Between 2007 and 2017, PDP responsibility for the basic non-Low Income Subsidy (non-LIS) benefit dropped significantly from 53 percent to 29 percent while the PDP responsibility for the basic LIS benefit dropped from 30 percent to 19 percent. Meanwhile, Medicare’s share of benefits rose commensurately through reinsurance and LIS. According to a MedPac June 2020 report to Congress: “The magnitude of decreases in plans’ share of [Part D] benefit liability raises significant concerns because it shifts substantial financial risk to the Medicare program and taxpayers and undermines a key feature of the Part D program: providing incentives for competing private plans that bear insurance risk for their enrollees’ spending to negotiate prices with pharmacies and pharmaceutical manufacturers.”²⁷

76. The MedPac concerns were in no small part the result of the collusion across CVS

²⁷ MedPac, Chapter 5: *Realigning incentives in Medicare Part D* (June 2020), at 120.

Health subsidiaries to require SilverScript formularies to include only more expensive brand-name drugs instead of lower cost, generic drugs.

D. Maintaining an Effective Compliance Program Is a Prerequisite for a PDP Sponsor to Obtain and Retain Part D Payments

77. PDP Sponsors' obligations to the Medicare Program and the requirements for them to participate in the Program are set forth in CMS regulations and, each year, the PDP Sponsors must agree in writing to comply with those regulations.²⁸ In addition, PDP Sponsors must comply with requirements set forth in statutes, such as the FCA, and guidance documents, such as the Medicare Managed Care Manual and the Medicare Prescription Drug Benefit Manual.

78. Among their other obligations, Medicare PDP Sponsors are required²⁹ to (i) maintain a compliance program to ensure the integrity of their payment data³⁰; (ii) annually attest to the accuracy and truthfulness of that data³¹; and (iii) "comply with . . . Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law [and] the False Claims Act (31 USC §§ 3729 et seq.)."³²

79. Medicare PDP Sponsors are required³³ (i) to ensure the integrity of their payment

²⁸ 42 C.F.R. §§ 423.504, 423.505.

²⁹ 42 C.F.R. § 423.504(b)(4)(vi); IOM Pub. 100-18 Prescription Drug Benefit Manual Chapter 9.

³⁰ 42 C.F.R. § 423.504(b)(4)(vi).

³¹ 42 C.F.R. § 423.505(k).

³² 42 C.F.R. § 423.

³³ 42 C.F.R. § 423.504(b)(4)(vi); IOM Pub. 100-18 Prescription Drug Benefit Manual Chapter 9.

data³⁴; (ii) annually attest to the accuracy and truthfulness of that data³⁵; and (iii) “comply with . . . Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law [and] the False Claims Act (31 USC §§ 3729 et seq.).”³⁶

80. CMS requires PDP Sponsors must have a compliance program which is effective in detecting, correcting, and preventing Medicare program noncompliance.³⁷

81. The implementation of an effective compliance program is a prerequisite to a PDP Sponsor obtaining and retaining payments under Part D of the Medicare Program.³⁸ One purpose of requiring a compliance program is to ensure that the PDP Sponsor submits accurate and truthful information to CMS.

82. The compliance program “must, at a minimum, include [certain] core requirements,”³⁹ including (but not limited to):

...

(F) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the PDP, including first tier entities’,

³⁴ 42 C.F.R. § 423.504(b)(4)(vi).

³⁵ 42 C.F.R. § 423.505(k).

³⁶ 42 C.F.R. § 423.

³⁷ 42 C.F.R. § 423.504(b)(4)(vi).

³⁸ *Id.*

³⁹ 42 C.F.R. § 422.504(b)(4)(vi).

compliance with CMS requirements and the overall effectiveness of the compliance program.

(G) Establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensuring ongoing compliance with CMS requirements.

(1) If the PDP organization discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.

(2) The PDP organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation.

(3) The PDP organization should have procedures to voluntarily self-report potential fraud or misconduct related to the Plan to CMS or its designee.⁴⁰

83. As part of an effective compliance program, a Sponsor must establish and implement systems to monitor and audit its First Tier, Downstream, and Related Entities (“FDRs”). Sponsors may enter into contracts with FDRs to provide administrative or health care services for enrollees on behalf of the Sponsor (*e.g.*, a PBM or a Call Center). However, the Sponsor maintains the ultimate responsibility for fulfilling the terms and conditions of its contract with CMS, and for meeting the Medicare program requirements.

⁴⁰ 42 C.F.R. § 422.504(b)(4)(vi)(F)-(G).

84. In its compliance training materials, CMS has spelled out the requirement that Part D Sponsors must “implement and maintain an effective compliance program for its Medicare Parts C and D plans.” Furthermore, the CMS training states “[a]n effective compliance program must”:

- Articulate and demonstrate an organization’s commitment to legal and ethical conduct;
- Provide guidance on how to handle compliance questions and concerns; and
- Provide guidance on how to identify and report compliance violations.⁴¹

85. CMS further defines an effective compliance program as one that “fosters a culture of compliance within an organization” and “promotes the organization’s Standards of Conduct.”⁴²

86. A fundamental part of compliance with CMS’s Medicare Part D requirements is acting ethically and honestly. CMS states that, “[a]s part of the Medicare Program, [a Part D Plan] must conduct [itself] in an ethical and legal manner. It’s about doing the right thing!” To do so, a Part D Plan must, “[a]ct fairly and honestly, [a]dhere to high ethical standards in all [it does], [c]omply with all applicable laws, regulations, and CMS requirements, [and r]eport suspected violations.”⁴³

87. Non-compliant conduct is conduct that does “not conform to the law, Federal health care program requirements, or an organization’s ethical and business policies.”⁴⁴ Areas CMS has

⁴¹ Medicare Parts C and D General Compliance Training Web-Based Training Course January 2019, available at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/MedCandDGenCompdownload.pdf>.

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.*

identified as high risk include appeals and grievance review, ethics, as well as pharmacy, formulary, and benefit administration.⁴⁵

88. CVS Health's own training module for its 2018 Medicare Part D Annual Certification of Compliance (the "Module") mirrors CMS guidance nearly verbatim, acknowledging its obligation to act ethically, legally, fairly, and honestly.⁴⁶

89. The CVS Health Module clearly defines fraud, waste and abuse as "knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program, or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program."⁴⁷ It further explains "abuse" as "actions that may, directly or indirectly, result in unnecessary costs to the Medicare Program. Abuse involves payment for items or services when there is not legal entitlement to that payment and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment."⁴⁸ Waste is the overutilization of services, or other practices that, directly or indirectly, results in unnecessary costs to the Medicare program.

90. The Module acknowledges the role all of the various CVS Health components play in combatting fraud, waste, and abuse ("FWA"),⁴⁹ including the CMS Contractor (Part D Plan

⁴⁵ *Id.*

⁴⁶ SilverScript, *2018 Annual Certification Medicare Parts C and D General Compliance & Combating Fraud, Waste, and Abuse Training Course* (January 2017), p. 11, available at <http://pfsinsurance.com/wp-content/uploads/2018-SilverScript-Certification-Guide.pdf>.

⁴⁷ *Id.* at 31.

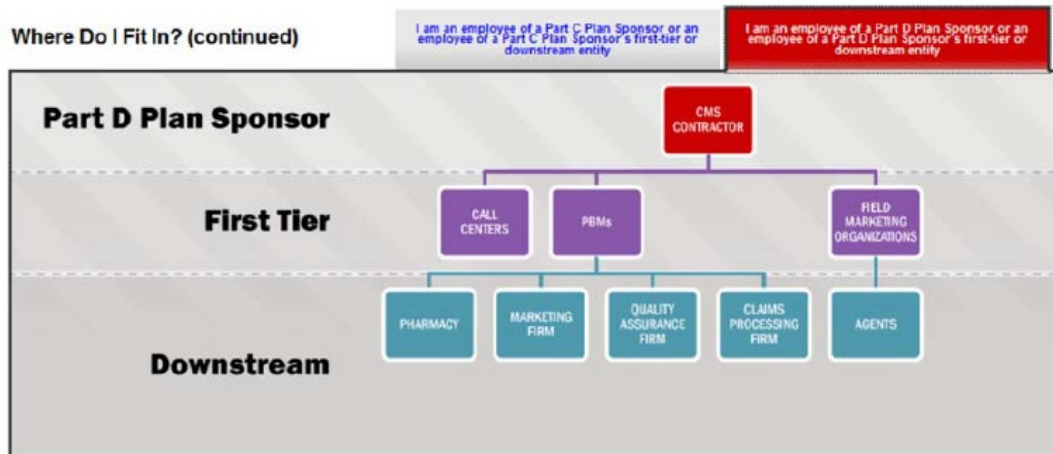
⁴⁸ *Id.* at 32.

⁴⁹ *Id.* at 49.

Sponsor), PBMs (First Tier) and pharmacies (Downstream):

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Lesson 2: Your Role in the Fight Against FWA



91. The Module also explains that beyond the ethical guidelines spelled out by CMS, CVS Health incorporates into its compliance plan its Code of Conduct, which states its “expectations and the principles and values” by which it operates.⁵⁰

92. In turn, the CVS Health Code of Conduct spells out its commitment to “upholding the highest ethical standards and complying with applicable laws and regulations” and “federal health care program requirements.”⁵¹ In all its dealings with customers, CVS Health says its interactions will “help us put people on a path to better health.”⁵²

93. The Code of Conduct says the company is committed to “Doing the Right Thing.”⁵³ This means that, in undertaking all of its “contractual promises,” while it strives to outperform its

⁵⁰ *Id.* at 12.

⁵¹ CVS Health Code of Conduct (2019) at 4, available at <https://cvshealth.com/sites/default/files/cvs-health-code-of-conduct.pdf>.

⁵² *Id.* at 21.

⁵³ *Id.* at 26.

competition, it will “do so honestly, openly, fairly and with integrity. We will deal fairly with our customers, members, providers, clients, suppliers, regulators, shareholders and others around the world with whom we do business.” The Code very clearly states CVS Health will refuse to participate in any conduct “intended to mislead, manipulate or take unfair advantage of anyone. . .”⁵⁴

94. The Code also makes clear that choosing not to follow a Medicare Program policy “could be interpreted by the government as fraud or payment abuse.”⁵⁵ Likewise, its Code of Conduct is the “underlying framework for our Medicare Compliance Program. . . .”⁵⁶

95. The Code includes this specific language concerning “Business firewalls”:

As a good business practice, CVS Health maintains firewalls between select businesses within the Company to separate and protect certain competitively-sensitive information each business possesses. Colleagues may not use competitively sensitive information that is held by the Company, to compete unfairly in the marketplace. Competitively sensitive information includes contract terms, pricing and other financial arrangements. These firewalls become important in contract negotiations, bid preparation, pricing services, and establishing financial arrangements, in which the businesses must compete on the same terms as their competitors. Information firewalls also maintain commercial relations with CVS Health clients and suppliers who may be competitors to certain CVS Health business units.

96. The 2019 version of the Code also explained that CVS Health had entered into two (2) Corporate Integrity Agreements (“CIAs”) with the HHS Office of the Inspector General in 2014 and 2016 as part of settlements for alleged wrongdoing related to Federal health care fraud. Its 2014 CIA states, for example, that CVS Health “in accordance with the terms of the CIA” has

⁵⁴ *Id.*

⁵⁵ *Id.* at 27-28.

⁵⁶ *Id.* at 29.

implemented a compliance program to cover all parts of the corporation that “conduct business with Federal health care programs.”⁵⁷

97. These CIAs reinforce the CVS Health “strong commitment to compliance with the law and the highest ethical standards of our colleagues.”⁵⁸

98. The Code spells out the obligation of CVS Health leadership to “walk the talk” and “demonstrate the Company’s values in all of their dealings on its behalf.” CVS Health leadership is to “[m]ake certain that colleagues understand what is expected of them both professionally and ethically.”⁵⁹

E. PDP Sponsors Are Obligated to Provide Beneficiaries a Full and Fair Process for Grievances and Coverage Determinations

99. A PDP Sponsor’s central mission is to provide beneficiaries access to needed Part D drugs through their prescription drug benefits within a framework of Medicare Part D requirements that provide enrollees with a number of protections.

100. As alleged herein, there is an underlying obligation that PDP Sponsors must act ethically and honestly in all their dealings with Medicare Part D Beneficiaries. For example, Medicare beneficiaries have clearly spelled out rights and protections. For example, the CMS guidance states that “[n]o matter how you get your Medicare, you have certain rights and protections designed to [p]rotect you when you get health care[;] [m]ake sure you get the health

⁵⁷ Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and CVS Health Corporation, at 2, available at https://oig.hhs.gov/fraud/cia/agreements/CVS_Health_Corporation_10112016.pdf.

⁵⁸ *Id.* at 32.

⁵⁹ *Id.* at 34.

care services that the law says you can get[;] and [p]rotect you against unethical practices.”⁶⁰

101. A Medicare beneficiary is entitled to “[g]et clear and simple information about Medicare to help you make health care decisions, including [w]hat’s covered[;] [w]hat Medicare pays[;] [h]ow much you have to pay[;] [and w]hat to do if you want to file a complaint or an appeal.”⁶¹

102. A Medicare beneficiary is entitled to “[r]equest an appeal to resolve differences with your plan. You have the right to ask your plan to provide or pay for an item or service you think should be covered, provided, or continued. If your plan denies your request, you have the right to appeal that decision.”⁶²

103. A Medicare beneficiary is entitled to “[g]et a coverage decision or coverage information from your plan before getting services. Before you get an item, service, or supply, you can call your plan to find out if it will be covered or get information about your coverage rules. You can also call your plan if you have questions about home health care rights and protections. Your plan must tell you if you ask.”⁶³

104. Medicare Part D requirements⁶⁴ apply to stand-alone PDP Sponsors like SilverScript that offer prescription drug benefits directly to beneficiaries. Sponsors are required

⁶⁰ CMS, *Medicare Rights & Protections*, at 5 (rev. Jan. 2018), available at <https://www.medicare.gov/Pubs/pdf/11534-medicare-rights-and-protections.pdf>.

⁶¹ *Id.* at 6.

⁶² *Id.* at 11.

⁶³ *Id.* at 12.

⁶⁴ See 42 C.F.R. § 423, Subpart M: IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18.

to enter into an agreement with CMS by which the Sponsor agrees to comply with a number of requirements based upon the Medicare Part D statute, regulations, and program instructions.

105. A Sponsor's grievance and coverage determination operations serve as a "safety net" for improper formulary administration.⁶⁵

106. Improper processing of grievances and coverage determinations denies beneficiaries due process and appeal rights and may delay a beneficiary's access to medically necessary or life-sustaining services or drugs.⁶⁶

107. Medicare enrollees have the right to contact their PDP Sponsor to express general dissatisfaction with the operations, activities, or behavior of the PDP Sponsor or to make a specific complaint about the denial of coverage for drugs or services to which the enrollee believes he or she is entitled.

108. Federal regulations authorize CMS to impose intermediate sanctions (such as suspension of enrollment and marketing), civil monetary penalties, or to terminate PDPs if it determines that medically necessary items and services have not been provided as required.⁶⁷

109. SilverScript has been a serial offender under the CMS enforcement regime. For example, SilverScript received a serious enrollment sanction on January 1, 2013, suspending all enrollment of Medicare beneficiaries (pursuant to 42 C.F.R. § 423.750(a)(1)) and all marketing

⁶⁵ CMS Letter to Smart Insurance Company, *Notice of Immediate Imposition of Intermediate Sanctions (Suspension of Enrollment and Marketing) for Prescription Drug Plan Contract Number: S0064*, at 5 (April 23, 2013), available at https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/Smart-Immediate-Sanction-4_23_2013.pdf.

⁶⁶ *Id.*

⁶⁷ 42 C.F.R. §§ 423.7500; 423.752(a); 423.509(a).

activities to Medicare beneficiaries (pursuant to 42 C.F.R. § 423.750(a)(3)). CMS imposed

“intermediate sanctions immediately, effective January 15, 2013 at 11:59 p.m. EST, pursuant to 42 C.F.R. § 423.756(c)(2), because it has determined that [SilverScript’s] conduct poses a serious threat to the health and safety of Medicare beneficiaries. A significant number of the [SilverScript] enrollee complaints describe instances where the member had to pay more out of pocket than was required under the terms of the benefit plan because [SilverScript] systems could not correctly adjudicate the member’s claims in real time. For some beneficiaries, this meant paying a higher copay amount while others were charged the full cost of the drug. In many instances, beneficiaries could not afford the higher charge and left the pharmacy without their medication. SSIC has acknowledged to CMS that many of its enrollees have had difficulty obtaining their medications or are being charged incorrect co-pay or cost-sharing amounts.

110. As part of imposing these very serious sanctions, CMS determined that:

- “[SilverScript] substantially failed to carry out the terms of its Prescription Drug Plan contract with CMS (42 C.F.R. §423.509(a)(1)); and
- [SilverScript] is carrying out its contracts with CMS in a manner that is inconsistent with the effective and efficient implementation of the program (42 C.F.R. §423.509(a)(2)).”

111. Even after it released SilverScript from these sanctions in late 2013, CMS said it still “considers [SilverScript] to be a high-risk sponsor, and will continue to closely monitor and oversee [SilverScript’s] operational activities. [SilverScript] will be subject to targeted monitoring, including heightened surveillance and oversight.”

112. Just two years later, on November 20, 2015, CMS sent a Notice of Imposition of Civil Money Penalty to SilverScript, fining it \$594,100 based on the fact that it had failed to provide beneficiaries with prescription drug benefits within a framework of Medicare requirements.⁶⁸

⁶⁸ See CMS letter to SilverScript (Nov. 20, 2015), https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/SilverScript_CMP_11_20_2015.pdf.

113. Coming off these two CMS sanctions, SilverScript was particularly concerned that its conduct not be subject to sanctions again. Rather than toe the line, instead this has meant that it took what it knew to be measures to conceal its illegal conduct. For example, SilverScript knew what triggered the 2013 sanctions was that CMS had detected patterns in beneficiary grievances. SilverScript also knew that CMS continued to monitor trends in its beneficiary grievances even after it had been released from the sanctions in late 2013. As a result, SilverScript made sure that the SSG/DNS Scheme would not apply to new enrollees whose grievances would immediately draw increased attention during CMS audits.

114. Likewise, after CVS Health and its subsidiaries entered into the Harvoni and Epclusa deals with Gilead in late 2018, rather than carefully monitoring member grievances to ensure it was acting legally, CVS Health took steps to make sure its conduct would not be uncovered.

115. In all other circumstances, CVS Health used a formal root cause tagging system for grievances to track trends and monitor for member disruption. This system was used frequently to tag actual drug names in cases of formulary disruption or potential member dissatisfaction when a drug is not covered.

116. During a December 17, 2018 meeting, Ms. Miller was instructed that, rather than use its formal tagging system, she was to informally monitor beneficiary grievances for Harvoni and Epclusa behind the scenes to watch for any “member disruption” and/or grievances related to generic block for these drugs, and notify management.

117. It was highly unusual for this monitoring to be done informally in this way, but it was the only way to prevent a paper trail (showing that CVS Health was concerned about members being disrupted) and also was the only way to keep front-line colleagues from being asked about

trends, which would create more risk for CVS.

118. When she raised concerns with Emily Pefanis, Vice President Medicare Operations, on January 11, 2019, Ms. Pefanis said the blocking scheme was “highly unethical” and that she had had multiple conversations about the issue with Amy Moyer-Carey, Vice President Coverage Determinations, who was apparently “sick over this.” However, Ms. Moyer-Carey had been told by Mitch Betses (EVP Member Services), Todd Meek (President of SilverScript), and Patrick Jeswald (Chief Compliance Office, Medicare Part D) that “this is a new strategy,” and they were to do this anyway.

119. With regard to the conduct at issue, a PDP Sponsor like SilverScript that fails to meet Part D grievance and coverage determination requirements has impeded enrollees’ access to medications. This failure violates 42 C.F.R. §§ 423.564(b) and 423.566, subjecting the PDP Sponsor to a Civil Money Penalty⁶⁹ because it has directly and adversely affected (or had the substantial likelihood of adversely affecting) enrollees’ access to medications.

1. Grievances

120. According to the Medicare Modernization Act, all PDP Sponsors must provide meaningful procedures for hearing and resolving grievances between an enrollee and the Sponsor, including an entity or individual through which the Sponsor provides benefits.⁷⁰

121. A grievance is any complaint or dispute, other than a coverage determination, or appeal about any aspect of the operations, activities, or behavior of a Part D organization,

⁶⁹ 42 C.F.R. §§ 423.752(c)(1); 423.760(b).

⁷⁰ CMS, Medicare Part D Reporting Requirements (Jan. 1, 2020), <https://www.cms.gov/files/document/cy2020part-d-reporting-requirements082719.pdf>.

regardless of whether remedial action is requested.⁷¹

122. PDP Sponsors are required to notify enrollees of their decision no later than 30 days after receiving their grievance based on the enrollee's health condition. An extension up to 14 days is allowed if it is requested by the enrollee, or if the PDP Sponsor needs additional information and documents that this extension is in the interest of the enrollee. An expedited grievance that involves refusal by a PDP Sponsor to process an enrollee's request for an expedited coverage determination or redetermination requires a response from the PDP Sponsor within 24 hours.⁷²

2. Coverage Determinations

123. The first level of review is the coverage determination, which is conducted by the PDP Sponsor, and the point at which beneficiaries or their physicians submit justification for the benefit. The enrollee, the enrollee's representative, or the enrollee's treating physician or prescriber may make a request for a coverage determination.

124. Each PDP Sponsor must conduct meaningful and thorough coverage determinations and redeterminations by attempting to contact prescribing physicians or other prescribers to obtain supporting statements and additional medical documentation necessary to evaluate a request, as appropriate.

125. If the coverage determination is adverse (not in favor of the beneficiary), the beneficiary has the right to file an appeal. The first level of the appeal – called a redetermination (Part D) – is handled by the PDP Sponsor and must be conducted by a physician who was not involved in the organization determination or coverage determination decision. If the first level appeal is adverse, a second level of appeal – called a reconsideration (Part D) – is made to an

⁷¹ *Id.*

⁷² *Id.*

independent review entity (“IRE”) contracted by CMS.

126. There are different decision-making timeframes for the review of coverage determinations. If the Sponsor does not issue timely decisions for Part D coverage determinations or redeterminations, the decision is considered to be unfavorable to the enrollee and must be automatically sent to the IRE. Failure to provide enrollees and/or their providers, notice of decisions for coverage determinations or appeals within the required timeframes can result in enrollees failing to receive the approved services or reimbursement, or delays with accessing services and/or appeal rights.

F. FDA Approval of Generic and “Authorized Generic” Drugs

127. When a brand-name pharmaceutical manufacturer receives approval from the Food & Drug Administration (“FDA”) to market a new pharmaceutical, the manufacturer typically receives a period of “exclusivity” during which it has the sole right to market the drug in the United States. In addition to the FDA exclusivity period, the brand-name manufacturer typically holds patent rights that prevent competitors from producing and marketing the same chemical compound. Because brand-name manufacturers market their drugs under a proprietary name rather than the name of the drug’s generic active ingredient, they are referred to as “brand-name drugs.”

128. After the exclusivity period and patent rights expire, however, other pharmaceutical manufacturers may submit to the FDA an Abbreviated New Drug Application (“ANDA”) and receive approval to market a generic version of the brand-name drug.

129. Congress has made clear that access to less costly equivalent generic pharmaceuticals is to be encouraged, and, to that end, in 1984 enacted the Hatch-Waxman Act (“Hatch-Waxman”), which established an abbreviated pathway for approval of generic counterparts to non-biologic brand-name drug products.

130. A principal goal of Hatch-Waxman was to trigger generic access to originator

products, many of which had enjoyed longstanding exclusivity. That goal has been achieved: According to the FDA, the competition spurred by Hatch-Waxman has saved more than \$1.6 trillion for patients and the health care system.⁷³

131. A “generic drug,” as that term is commonly understood and referred to by health care providers and insurers, is a copy of a brand-name drug that is developed and made by a company other than the company that makes the brand-name drug. A generic drug is the same as the brand-name drug in active ingredient, conditions of use, dosage form, strength, route of administration, and (with certain permissible differences) labeling. However, a generic drug may have certain minor differences from the brand-name product, such as different inactive ingredients.

132. To obtain approval of a generic drug, a company must submit an ANDA to FDA and prove that its product is the same as the brand-name drug in the ways described above, and that it is “bioequivalent,” meaning it gets to the part of the body where the drug works at the same time and in the same amount. A generic drug must also meet the same standards of quality and manufacturing as the brand-name drug. An ANDA applicant is not required to provide independent evidence of the safety and effectiveness of a proposed generic drug. Instead, the applicant relies on FDA’s finding that a previously approved drug product is safe and effective. Therefore, it is generally less costly to obtain approval of a generic drug than a brand-name drug.

133. The term “authorized generic” drug is most commonly used to describe an approved brand-name drug that is marketed without the brand-name on its label. Other than the fact that it does not have the brand-name on its label, it is the exact same drug product as the brand-

⁷³ See Kathleen “Cook” Uhl, *2016: A Record-Setting Year for Generic Drugs*, U.S. Food & Drug Administration (Feb. 24, 2017), available at <https://blogs.fda.gov/fdavoices/index.php/2017/02/2016-arecord-setting-year-for-generic-drugs/> (noting that “2016 was a record-setting year for FDA’s generic drug program,” and that “[o]ver the last 10 years, generic drugs have saved the U.S. healthcare system about \$1.68 trillion”).

name product. An authorized generic may be marketed by the brand-name drug company, or another company with the brand company's permission. In some cases, even though it is the same as the brand-name product, a company may choose to sell the authorized generic at a lower cost than the brand-name drug.

134. An authorized generic drug is the same as the brand-name drug, but does not use the brand-name on the label. Because an authorized generic drug is marketed under the brand-name drug's NDA, it is not listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book").

135. An authorized generic is considered to be therapeutically equivalent to its brand-name drug because it is the same drug. This is true even if the brand-name drug is "single source," meaning there are no ANDAs approved for that product, or coded as non-equivalent by the FDA in the Orange Book. While a separate NDA is not required for marketing an authorized generic, FDA requires that the NDA holder notify the FDA if it markets an authorized generic. The NDA holder may market both the authorized generic and the brand-name product at the same time.

136. FDA publishes a list of reported authorized generics and updates that list quarterly.⁷⁴

137. To be clear, these are "generics" in name only. In fact, these products are the actual brand-name medications. They are simply marketed as a generic for price and insurance purposes. To be clear, these are "generics" in name only. In fact, these products are the same as brand-name medications, but may have a different color or marking. They are simply marketed as a generic for

⁷⁴ See, e.g., FDA Listing of Authorized Generics (April 1, 2020), available at <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/fda-listing-authorized-generics>.

price and insurance purposes.

138. This often happens when the brand-name drug is nearing its patent expiration.⁷⁵ For example, to forestall competition from a generic manufacturer, the brand manufacturer strikes a deal: in exchange for dismissal of pending patent infringement litigation, the generic manufacturer (often a division of the brand manufacturer) can market its brand-name drug as an authorized generic if it delays making its own generics for a certain period of time.

139. For the brand company, an authorized generic launch may provide a means to hold onto some of the monopoly revenue it would lose from the termination of brand-name exclusivity that would otherwise go to the generic first-filer.

G. PDP Sponsors Are Obligated to Provide Beneficiaries Information about Access to Generic Drugs, Including Information About Differential Pricing for Less Costly Generic Drugs

1. Medicare Part D Relies on Health Plans Competing Vigorously to Drive Adoption of Less Costly Generic Drugs.

140. Policymakers have long recognized the need for robust generic competition to help bring down the cost brand-name prescription drug costs.⁷⁶ The Medicare Part D prescription drug program – which covers 43 million American elderly, ESRD and disabled beneficiaries – relies on the assumption that health plans like SilverScript would vigorously compete to drive adoption of less costly generic drugs.⁷⁷

⁷⁵ *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, Federal Trade Commission (Aug. 2011).

⁷⁶ See, e.g., Minority Staff of the U.S. Senate Committee on Finance, *A Tangled Web: An Examination of the Drug Supply and Payment Chains* (June 2018), at viii.

⁷⁷ Kaiser Family Foundation, *An Overview of the Medicare Part D Prescription Drug Benefit* (October 2018), <https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/>.

141. However, Part D plans like SilverScript have instead often preferred higher-cost brand-name products over lower-cost generics, blocking beneficiary access to generics and generating additional costs to the Medicare program as well as to elderly, ESRD and disabled beneficiaries.

142. Specifically, CMS has noted there are “instances when Part D sponsors are not including generic alternatives when available. Instead, sponsors are covering only the brand drugs, which decreases generic substitution and increases beneficiary costs.”⁷⁸

2. Medicare Requires PDPs to Advise Beneficiaries of the Cost Differential for the Lowest Price Generic Alternative.

143. As part of the requirement that drugs are provided economically to the Government, Medicare requires PDP Sponsors to have a “cost-effective drug utilization management program.” This provision specifically requires PDP Sponsors have “incentives to reduce costs when medically appropriate, such as through the use of multiple source drugs.”⁷⁹ Thus, Medicare explicitly recognizes that generics drugs can provide Medicare and Part D beneficiaries with more affordable alternatives and should be utilized.

144. Medicare Part D not only requires Sponsors to reduce costs through making multiple source drugs available to beneficiaries, the statute also states that Sponsors are to require that pharmacies that dispense drugs covered by Part D must advise beneficiaries of any differential between the price of the drug to the enrollee and the price of the lowest-priced equivalent generic

⁷⁸ Centers for Medicare & Medicaid Services, *Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* (April 2019), <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf>.

⁷⁹ 42 U.S.C.A. § 1395w-104(c)(1)(A).

that is therapeutically equivalent and bioequivalent available at the pharmacy.⁸⁰

145. In its June 28, 2005 Final Regulations, CMS explained this disclosure requirement as follows:

Under section 1860D–4(k) of the Act, Part D plans must provide that each pharmacy in their networks complies with the requirement to disclose to beneficiaries information about less expensive therapeutically equivalent and bioequivalent covered Part D drugs. Specifically, Part D plans must provide information about the differential between the price of the covered Part D drug to the enrollee (factoring in any applicable cost-sharing) and the price of the lowest-priced therapeutically equivalent and bioequivalent drug available at that pharmacy.⁸¹

146. Section § 423.132 makes clear the disclosure requirements: “[A] Part D sponsor must require a pharmacy that dispenses a covered Part D drug to inform an enrollee of any differential between the price of that drug and the price of the lowest priced generic version of that covered Part D drug that is therapeutically equivalent and bioequivalent and available at that pharmacy, unless the particular covered Part D drug being purchased is the lowest-priced therapeutically equivalent and bioequivalent version of that drug available at that pharmacy.”⁸²

147. Nor is the disclosure requirement limited only to instances in which the beneficiary requested the generic pricing information. Industry comments to the proposed regulations asked that pharmacies not be required to disclose pricing information unless the beneficiary had requested this information. CMS rejected this suggestion, responding that pharmacies must in all

⁸⁰ Medicare Modernization Act § 1860D-4 (k)(1); 42 U.S.C. 1395w-104(k)(1).

⁸¹ Final Regulations, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4274 (Jan. 28, 2005).

⁸² *Id.* at 4446. *See also* CMS, Prescription Drug Benefit Manual, Chapter 5: Benefits and Beneficiary Protections, at 70 (Sept. 20, 2011), available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf.

instances disclose the price of equivalent generic drugs because this requirement is designed to protect against withholding “valuable” information of which consumers may not be aware and “will save money for beneficiaries, PDPs, and Medicare”:

Comment: One commenter concerned with the burden on pharmacies to disclose pricing information stated that the disclosure requirement should be limited to cases in which an enrollee asks for this information at the pharmacy.

Response: . . . **Part D plans must require network pharmacies**, except for those which we have specifically exempted from the requirement, **to disclose information about price differentials. We cannot limit this requirement to circumstances in which an enrollee specifically asks for the information.** Furthermore, **we believe such disclosure will provide enrollees—many of whom may not know that less expensive generic equivalents are available—with valuable information that will save money for beneficiaries, Part D plans, and Medicare.**⁸³

148. Likewise, CMS rejected limiting pricing disclosure to only those instances when the prescriber has stated “Do Not Substitute” (*i.e.*, DAW 2) because disclosing prices for less costly generics provides “valuable information that will save money for beneficiaries, Part D plans, and Medicare”:

Comment: One commenter recommended disclosure only when a brand-name drug is prescribed and the prescriber has not stated “Do Not Substitute.”

Response: . . . Part D plans must require network pharmacies, except for those which we have specifically exempted from the requirement, to disclose information about price differentials. **We cannot limit this requirement to circumstances in which a prescriber has written a prescription for a brand-name drug and has not specifically stated that the pharmacy must not substitute the brand-name drug for a generic drug. We believe such disclosure will provide enrollees many of whom may not know that less expensive generic equivalents are available with valuable information that will save money for beneficiaries, Part D plans, and Medicare.**⁸⁴

149. Furthermore, the comments make clear that the Medicare PDP Sponsor is to ensure

⁸³ *Id.* at 4725 (emphasis added).

⁸⁴ *Id.* (emphasis added).

the pharmacies in its network comply with the requirement to disclose price differentials for less costly generic options: “Under section 1860D–4(k) of the Act, PDPs must provide that each pharmacy in their networks complies with the requirement to disclose to beneficiaries information about less expensive, therapeutically equivalent, and bioequivalent covered Part D drugs. Specifically, PDPs must provide information about the differential between the price of the covered Part D drug to the enrollee (factoring in any applicable cost sharing) and the price of the lowest priced therapeutically equivalent and bioequivalent drug available at that pharmacy.”⁸⁵

150. As recently as May 17, 2018, then CMS Administrator Seema Verma reminded PDP Sponsors “that they must require their network pharmacies to disclose any differential between the price of a Part D drug and the price of the lowest cost therapeutically-equivalent generic version of that Part D drug.”⁸⁶

H. CMS Requires Pharmacies to Report “Accurate, Complete and Truthful” Generic Substitution Instructions as Part of Each Part D Claim

1. Plans Must Submit Accurate DAW Coding as Part of Each Claim

151. CMS requires Plan Sponsors to submit data, referred to as PDEs, for each prescription for which the Plan Sponsor has paid.⁸⁷ PDE data are used, in part, to validate claims, monitor quality, and make year-end risk corridor calculations.⁸⁸

152. When pharmacies dispense drugs to Medicare Part D enrollees, the pharmacies

⁸⁵ *Id.* at 4274.

⁸⁶ See Seema Verma letter to PDP Sponsors, *Unacceptable Pharmacy Gag Clauses* (May 17, 2018), available at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/Other-Content-Types/2018-05-17.pdf>.

⁸⁷ 42 C.F.R. § 423.329(b)(3) (“data collection”); CMS, Updated Instructions: Requirements for Submitting Prescription Drug Event Data, at 5 (Apr. 27, 2006) (“PDE Instructions”).

⁸⁸ *Id.* at 5-6.

submit claims electronically to the enrollees' PDP Sponsor (often via a PBM) comprised of several pieces of information, including the ingredient cost (the cost of the drug itself), a dispensing fee, and any sales or similar taxes paid, less any payments received from the enrollee and any rebates received from the drug's manufacturer or distributor.

153. CMS requires PDP Sponsors to submit PDE records containing 36 CMS and 20 NCPDP fields. The PDE Instructions explain that the PDP Sponsor is responsible for the submission of PDE data.⁸⁹ The PDE Instructions also state that, “[a]s a condition of payment, all Part D plans must submit data and information necessary for CMS to carry out payment provisions (§1860D-15(c)(1)(C) and (d)(2) of the Act, and 42 CFR §423.322).”⁹⁰

154. The PDE Instructions make clear that CMS “employ[s] the National Council for Prescription Drug Programs (NCPDP) industry standard whenever possible. Most data elements represent existing NCPDP fields where [CMS] employ[s] the same definition and field values that are currently in use per the NCPDP version D.0 drug claim standard.”⁹¹

155. “[E]ach data element and its specific potential use for CMS’s payment process” is included in the PDE Instructions.

156. Field 18 is particularly at issue here. Field 18 is entitled “DAW/Product Selection Code” and “indicate[s] the prescriber’s instruction regarding substitution of generic equivalents or order to dispense the specific product written.”⁹²

⁸⁹ *Id.* at 9 (“For each dispensing event, the plan must submit a prescription drug event or PDE record.”).

⁹⁰ *Id.* at 5.

⁹¹ *Id.* at 11.

⁹² *Id.* at 13.

157. Ten numbers (0-9), called DAW codes, may be entered into Field 18 of the PDE record to indicate information about the prescriber's generic substitution instructions or lack thereof. The DAW Code indicates whether a generic drug was substituted for a brand-name one, and if not, why no substitution was made.

158. The 2022 CMS PDE inbound file layout describes the DAW as follows:⁹³

FIELD NO.	FIELD NAME	NCPDP FIELD	POSITION	PICTURE	NCPDP, CMS OR PDFS DEFINED	DEFINITION / VALUES
18	DISPENSE AS WRITTEN (DAW) PRODUCT SELECTION CODE	408-D8	170 - 170	X(1)	NCPDP	0=No Product Selection Indicated 1=Substitution Not Allowed by Prescriber 2=Substitution Allowed - Patient Requested Product Dispensed 3=Substitution Allowed - Pharmacist Selected Product Dispensed 4=Substitution Allowed - Generic Drug Not in Stock 5=Substitution Allowed - Brand Drug Dispensed as Generic 6=Override 7=Substitution Not Allowed - Brand Drug Mandated by Law 8=Substitution Allowed Generic Drug Not Available in Marketplace 9=Other

159. NCPDP has defined the ten numbers for filling the DAW Code as:⁹⁴

CODE	DESCRIPTION
0	No Product Selection Indicated - This is the field default value that is appropriately used for prescriptions for single source brand, co-branded/co-licensed, or generic products. For a multi-source branded product with available generic(s), DAW 0 is not appropriate, and may result in a reject.
1	Substitution Not Allowed by Prescriber – This value is used when the prescriber indicates, in a manner specified by prevailing law, that the product is Medically Necessary to be Dispensed As Written. DAW 1 is based on prescriber instruction and not product classification.

⁹³ See CMS, "Prescription Drug Program (Part D)", <https://www.csscooperations.com/internet/csscw3.nsf/DID/C7NXNZ6PBK>

⁹⁴ *The Proper Use of the NCPDP® Telecommunication Standard Version D.0 as it applies to the Implementation of Medicaid Reimbursement Methodologies Based on Actual Acquisition Cost (AAC) Plus a Professional Dispensing Fee Version 1.1* April 2017, available at <https://www.ncdp.org/NCPDP/media/pdf/wp/NCPDPTelecommMedicaidReimbursement.pdf>.

2	Substitution Allowed-Patient Requested Product Dispensed-This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted and the patient requests the brand product. This situation can occur when the prescriber writes the prescription using either the brand or generic name and the product is available from multiple sources.
3	Substitution Allowed-Pharmacist Selected Product Dispensed-This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted and the pharmacist determines that the brand product should be dispensed. This can occur when the prescriber writes the prescription using either the brand or generic name and the product is available from multiple sources.
4	Substitution Allowed-Generic Drug Not in Stock-This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted and the brand product is dispensed since a currently marketed generic is not stocked in the pharmacy. This situation exists due to the buying habits of the pharmacist, not because of the unavailability of the generic product in the marketplace.
5	Substitution Allowed-Brand Drug Dispensed as a Generic-This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted and the pharmacist is utilizing the brand product as the generic entity.
6	Override-This value is used by various claims processors in very specific instances as defined by that claims' processor and/or its client(s).
7	Substitution Not Allowed-Brand Drug Mandated by Law-This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted but prevailing law or regulation prohibits the substitution of a brand product even though generic versions of the product may be available in the marketplace.
8	Substitution Allowed-Generic Drug Not Available in Marketplace-This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted and the brand product is dispensed since the generic is not currently manufactured, distributed, or is temporarily unavailable.
9	Substitution Allowed By Prescriber but Plan Requests Brand – Patient's Plan Requested Brand Product To Be Dispensed - This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted, but the plan's formulary requests the brand product. This situation can occur when the prescriber writes the prescription using either the brand or generic name and the product is available from multiple sources.

160. As the NCPDP has stated, “[p]armacy systems are coded to maintain compliance with the HIPAA-named NCPDP Telecommunication Standard and cannot alter the DAW code logic to support other situations. Manual exception override processes also create significant barriers to pharmacy workflow processes and negate training and policies that ensure standardization and compliance with the Telecommunication Standard.”⁹⁵

161. While Code 0 is the “default,” NCPDP makes clear that, for “a multi-source

⁹⁵ *Id.* at 7.

branded product with available generic(s), *DAW 0 is not appropriate, and may result in a reject.*”⁹⁶
(emphasis added)

162. CVS Caremark’s own “Caremark Participating Pharmacy Administrative Manual” includes guidance on DAW Codes as well. As the manual says, “CAREMARK supports the NCPDP standard (Dispense As Written) DAW codes. To ensure accurate reimbursement, always include the correct (DAW) code when you submit a claim.”⁹⁷

163. CVS Caremark’s Administrative Manual provides further guidance on DAW Codes:

Dispense As Written (DAW)
DAW 0 - NO DISPENSE AS WRITTEN (Substitution Allowed) (or no product selection indicated) <ul style="list-style-type: none"> • Use the DAW 0 code when dispensing a generic drug; that is, when no party (i.e., neither Prescribing Provider, nor pharmacist, nor Participant) requests the branded version of a multi-source product. • Use the DAW 0 code when dispensing a multi-source generic, even if the Prescribing Provider indicates the DAW code for the generic product and does not specify a manufacturer. • Also, use the DAW 0 code when dispensing single-source brands (e.g., Lipitor[®]), because generic substitution is not possible.
DAW 1 – PHYSICIAN writes DISPENSE AS WRITTEN <ul style="list-style-type: none"> • Use when the Prescribing Provider specifies the branded version of a drug on the hard copy prescription or in the orally communicated instructions. • If Participant requests brand, and it is not a Prescribing Provider-initiated instruction, transmit the DAW 2 code. (See following instruction.)
DAW 2 - PATIENT REQUESTED <ul style="list-style-type: none"> • Use this code when the Participant requested the branded drug even though the original prescription did not indicate "Dispense As Written".
DAW 3 - PHARMACIST SELECTED BRAND
DAW 4 - GENERIC NOT IN STOCK

⁹⁶ Authorized generics are considered single-source if the product is only available from one labeler. A product with an authorized generic will become multi-source when products are available from additional labelers.

⁹⁷ Exhibit 1 (CVS-002944).

<u>Dispense As Written (DAW) continued</u>
DAW 5 - BRAND DISPENSED, PRICED AS GENERIC <ul style="list-style-type: none"> • Use when dispensing a brand as a generic. • Claims submitted with DAW 5 will be reimbursed at the generic price.
DAW 6 - OVERRIDE
DAW 7 - SUBSTITUTION NOT ALLOWED; BRAND MANDATED BY LAW
DAW 8 - GENERIC NOT AVAILABLE
DAW 9 - OTHER
Remember: Most Participants have a choice between brand and generic drugs. However, in some programs, the Participant will pay the difference between the cost of the brand and the available generic drug. Accordingly, correct DAW submissions indicate if a penalty is applicable.

164. If a pharmacy dispenses a brand-name multisource drug (a drug for which there is a brand-name and approved generic alternative from another labeler), the pharmacy must provide the basis for its decision not to substitute a generic in the form of a “Dispense as Written/Product Selection Code,” or “DAW Code.”

165. CMS recognizes that “excessive use of certain DAW codes may raise red flags from an audit perspective, especially the use of DAW 1 on multi-source products. Review acceptable use of DAW 1 and DAW 9 codes with staff and emphasize appropriate documentation procedures.”⁹⁸

166. The PDP Sponsor then is to use the information provided by the pharmacies, reformat it, and submit it to CMS as part of the PDE record. CMS uses the PDE information at the end of the payment year when it reconciles its advance payments to the PDP Sponsor with the

⁹⁸ Centers for Medicare and Medicaid Services, *Pharmacy Self-Auditing: Control Practices to Improve Medicaid Program Integrity and Quality Patient Care; Booklet 4: Billing Practices*, December 2015, available at: <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/pharmacy-selfaudit-booklet4-billing-practice.pdf>.

costs the Sponsor has incurred throughout the year.

167. Medicare Part D requires that, as a condition of payment, all PDP Sponsors must submit data and information necessary for CMS to carry out Part D's payment provisions, including claims information provided by the pharmacy for use in the PDE.⁹⁹

168. PDP Sponsors like SilverScript are "Health Care Providers" and "Covered Entities" under the Health Insurance Portability and Accountability Act ("HIPAA").¹⁰⁰

169. As HIPAA Covered Entities, PDP Sponsors and pharmacies are required to comply with certain electronic data transmission standards that CMS has adopted by regulation for pharmacy claims processing, including standards developed by NCPDP.¹⁰¹

170. The CVS Pharmacies and all non-CVS owned pharmacies in its networks were also required by their contracts with CVS Caremark to comply with NCPDP's standards regarding the electronic processing of claims. For example, the CVS Caremark standard contract with network pharmacies required, for "on-line claim submissions," that the "Pharmacy Provider" "shall submit" "required fields identified in the NCPDP Telecommunication Standard format."

171. Relying on the integrity of the claim information provided by the PBM and/or the network pharmacies, PDP Sponsors certify to CMS that the PDE information is accurate, complete, and truthful. 42 C.F.R. § 423.505(k)(3), entitled "Certification of data that determine payment," provides in relevant part:

CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under §

⁹⁹ 42 U.S.C. § 1395w-115(c)(1)(C), (d)(2); 42 C.F.R. § 423.32.

¹⁰⁰ 42 U.S.C. 1320(d); 45 C.F.R. § 160.103.

¹⁰¹ See 45 C.F.R. § 162 *et seq.*

423.329(b)(3) ... **are accurate, complete, and truthful** and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, **the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data** and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement.¹⁰²

172. Section 423.329(b)(3) thus “relate[s] directly to the payment of Part D claims” and required the certification by SilverScript and its subcontractors that “the submitted data is accurate, complete and truthful.”¹⁰³

2. Inappropriate Use of DAW Codes May Be Indicative of Fraud, Waste and Abuse

173. DAW codes are a crucial part of the PDE submission for multiple reasons. As one state Medicaid system put it, the codes are “an integral part of accurate billing” and provide “the reason why a specific brand or generic is dispensed based on the prescriber’s instructions. Failure to accurately use DAW codes results in misinformation to the Pharmacy program and its decision making process. Misinformation on claims may also result in retrospective pharmacy review and/or recoupment. Inaccurate usage of DAW codes is among one of the discrepancies found during an audit”¹⁰⁴

174. CMS has specifically identified as an example of potential pharmacy fraud, waste and abuse the “inappropriate use of dispense as written (‘DAW’) codes.”¹⁰⁵ Furthermore, in a

¹⁰² 42 C.F.R. § 423.505(k)(3) (emphasis added).

¹⁰³ *U.S. ex rel. Fox Rx, Inc. v. Omnicare, Inc.*, 38 F.Supp.3d 398, 411 (S.D.N.Y. 2014).

¹⁰⁴ Alabama Medicaid Program, *Appropriate Utilization of Dispense As Written (DAW) Codes*, available at https://medicaid.alabama.gov/documents/4.0_Programs/4.3_Pharmacy-DME/4.3.2_Billing_Policy_Info/4.3.2_Appropriate_Utilization_DAW_Codes_10-3-12.pdf.

¹⁰⁵ Centers for Medicare and Medicaid Services, “Prescription Drug Benefit Manual, Chapter 9 -- Part D Program to Control Fraud, Waste and Abuse,” Rev. 5, 09-26-08 at 51.

December 2015 guidance document, CMS also asked pharmacies to “[c]onsider the risk for fraud, waste, or abuse if pharmacy staff members adjudicate claims with inaccurate product selection [DAW] codes.”¹⁰⁶

175. Whether a brand-name or generic drug ultimately is dispensed at the pharmacy starts with the prescriber writing the prescription. Most of the time a prescriber does not indicate one way or another whether the pharmacy should dispense the brand-name or the generic drug. In those cases, except in States that require mandatory generic substitution, the pharmacy is allowed to, and will typically, dispense the less costly option for the beneficiary and more profitable for the pharmacy. In limited circumstances, however, the prescriber may determine in his or her clinical judgment that a brand-name version of a drug is medically necessary. If that is the case, the prescriber indicates on the prescription in accordance with applicable law that the pharmacy is to dispense the brand-name product.¹⁰⁷

176. Once the prescription is received by the pharmacy, the pharmacy is responsible for

¹⁰⁶ Centers for Medicare and Medicaid Services, *Pharmacy Self-Auditing: Control Practices to Improve Medicaid Program Integrity and Quality Patient Care; Booklet 4: Billing Practices*, December 2015, available at: <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/pharmacy-selfaudit-booklet4-billing-practice.pdf>.

¹⁰⁷ While these seventeen state mandatory generic substitution laws differ slightly in how prescribers may override the obligation to substitute with the generic, they all generally require prescribers to indicate that the brand is medically necessary, and are explicitly required to write “dispense as written,” “no substitution allowed,” or similar clear instruction on hard-copy prescriptions or to select the “dispense as written” field for e-prescriptions.

selecting at the point of sale the DAW code to include on the PDE record.¹⁰⁸

177. When submitting PDE records for reimbursement, however, the PDP Sponsor is responsible for assuring and certifying that the information in the PDE – such as the DAW Code – is “accurate, complete, and truthful” and “acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement.”¹⁰⁹

178. The PDP Sponsor’s responsibility to ensure the accuracy, completeness, and truthfulness of the data “includes if the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement.”¹¹⁰

179. Which DAW code the pharmacy chooses (and which is then certified as accurate by the PDP Sponsor) is determined by several variables, such as the prescriber’s instructions, the patient’s request for a brand-name or generic drug, state pharmacy law, and whether there are different versions of the prescribed drug (*e.g.*, if there is a generic version and a brand-name version). The combinations of these variables result in scenarios that are reflected in the DAW Codes submitted as part of the PDE record.

¹⁰⁸ See *The Proper Use of the NCPDP® Telecommunication Standard Version D.0 as it applies to the Implementation of Medicaid Reimbursement Methodologies Based on Actual Acquisition Cost (AAC) Plus a Professional Dispensing Fee* Version 1.1 April 2017, available at <https://www.ncdp.org/NCPDP/media/pdf/wp/NCPDPTelecommMedicaidReimbursement.pdf>. (“[T]he data field Dispense as Written (DAW)/Product Selection Code (408-D8) is required to be sent by the pharmacy to the processor/PBM.”).

¹⁰⁹ 42 C.F.R. § 423.505(k)(3).

¹¹⁰ *Id.*

180. Medicare uses the NCPDP standards to define the proper use of DAW Codes.¹¹¹

The most up-to-date NCPDP standards, NCPDP Telecommunication Standard Version D.0 (2017), define DAW Code 0 as:

No Product Selection Indicated - This is the field default value that is appropriately used for prescriptions for single source brand, co-branded/co-licensed, or generic products. For a multi-source branded product with available generic(s), DAW 0 is not appropriate, and may result in a reject.

181. While the title of DAW Code 0 indicates that Code 0 is for use when “no product is selected,” the definition of DAW Code 0 indicates that it should only be used when dispensing generic products or single source brand-name products – not in every circumstance in which no product selection is indicated. As the NCPDP definitions make clear, a DAW Code 0 “is not appropriate” for brand-name drugs with an available generic.

182. The conclusion that DAW Code 0 is not the correct DAW code when dispensing a brand-name product that has an available generic is supported by numerous other sources, including CVS Health’s own internal guidance:

CVS Caremark’s Administrative Manual instructs pharmacists to “*Use the DAW 0 code when dispensing a generic drug*; that is, when no party (*i.e.*, neither Prescribing Provider, nor pharmacist, nor Participant) requests the branded version of a multi-source product.” (emphasis added).¹¹²

183. CVS’s Provider Manual also includes a Reject Code for using a DAW Code 0 when dispensing a brand-name drug with available generics: “DAW 0 cannot be submitted on a multi-source drug with available generics. 407-D7, 408-D8.”¹¹³

¹¹¹ See *Moeckel v. Caremark, Inc.*, 622 F. Supp. 2d 663, 683 (M.D. Tenn. 2007).

¹¹² Exhibit 1 (CVS-002944).

¹¹³ See CVS, “Reject Codes: Provider Manual Appendix B,” at p. 33 (June 1, 2019), <https://www.caremark.com/portal/asset/CVSCaremarkPayerSheetRejectCodes.pdf>

184. Use of DAW Code 0 is therefore false when dispensing brand-name products that have generics available. This means that in the seventeen states where generic substitution is required, there is no correct DAW Code when a pharmacy chooses not to dispense an available generic drug in favor of a more expensive brand-name drug. Any DAW Code submitted in those situations would thus be false.

185. It makes sense that the DAW codes would not cover situations in which a pharmacy chooses to violate state law by not substituting a generic. When substitution of a generic is mandatory, the correct action is for the pharmacist to substitute the generic product and use DAW Code 0 (unless there are other extenuating circumstances like the generic not being in stock or the patient requesting the brand-name specifically). Even if a formulary only covers the brand-name product, these seventeen mandatory generic substitution States require that, if the generic cash price is less costly for the beneficiary, the pharmacy must dispense the generic.¹¹⁴

186. Even in states that do not mandate generic substitution, DAW Code 0 is not correct when dispensing the brand-name product. Simply put, if a pharmacy dispenses a brand-name when a generic was available, the DAW code needs to reflect an accepted reason why.¹¹⁵ The DAW codes provide the acceptable reasons (*e.g.*, prescriber indicates that the brand-name is medically necessary (DAW Code 1), the patient requests the brand-name (DAW Code 2), the generic drug

¹¹⁴ In all but four mandatory substitution States (Florida, Minnesota, Nevada, and Tennessee), there is no requirement that the lower cost generic be on the formulary.

¹¹⁵ See *The Proper Use of the NCPDP® Telecommunication Standard Version D.0 as it applies to the Implementation of Medicaid Reimbursement Methodologies Based on Actual Acquisition Cost (AAC) Plus a Professional Dispensing Fee* Version 1.1 April 2017, <https://www.ncdpd.org/NCPDP/media/pdf/wp/NCPDPTelecommMedicaidReimbursement.pdf>. (“[The DAW] field was intended to communicate to the processor/PBM the prescriber’s instructions as to whether generic substitution is allowed, or alternate reasons as to why the multi-source brand-name product is being dispensed.”).

is not in stock (DAW Code 4, *etc.*). The most up-to-date version of the NCPDP DAW codes also includes DAW Code 9.¹¹⁶ NCPDP defines DAW Code 9 as:

Substitution Allowed By Prescriber but Plan Requests Brand – Patient’s Plan Requested Brand Product To Be Dispensed - This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted, **but** the plan’s formulary requests the brand product. This situation can occur when the prescriber writes the prescription using either the brand or generic name and the product is available from multiple sources.

187. Thus, if a pharmacy in a non-mandatory substitution state chooses to dispense a brand-name version of a drug because of formulary considerations even though there is a generic available, the proper Code is DAW Code 9 – not DAW Code 0. Because the pharmacy does not have an obligation to dispense a less costly generic, it can choose to dispense the brand-name version even though it is more expensive if the plan wishes it to do so.¹¹⁷ What the pharmacy cannot do, however, is to misrepresent the reason why it chose to dispense the brand-name drug.

188. Yet, following the instructions of the plan to dispense the brand-name drug and submitting the PDE with DAW Code 9 is not always correct. Using DAW Code 9 is incorrect if a pharmacy is in a mandatory substitution State when there are less costly generics available. Even though the DAW Code 9 can be used to indicate situations in which the plan requests the brand-name product instead of the generic, the DAW Code cannot be used to supersede state law. This Second Amended Complaint contains examples of DAW Code 9 being used when dispensing a

¹¹⁶ Previous versions just had an “other” category as Code 9. CMS’s 2022 PDE Inbound File Layout Effective 01/01/2022 also continues to use Code 9 as “Other.”

¹¹⁷ However, according to the CMS required provisions in the retail pharmacy contract include “Provisions governing informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary’s prescription, as well as any associated differential in price.” 42 CFR §423.132. One in fact did exist with the applicable authorized generics and the “enterprise wide benefit” CVS sought negated pharmacies fulfilling this CMS required contractual element.

brand-name product in violation of state mandatory substitution laws.

189. As part of the PDE record, SilverScript had to submit accurate DAW coding information indicating that the brand-name versions of the SSG/DNS Drugs were dispensed at the pharmacy in order to receive the correct – *i.e.*, higher – reimbursement amounts for the brand-name versions.

190. A pharmacy may only lawfully dispense a brand-name product in States requiring generic substitution in very limited circumstances. These circumstances include when the prescriber specifies that substitution is not allowed (DAW Code 1), when the generic product is not in stock (DAW Code 4), when prescriber has indicated that generic substitution is permitted and the pharmacist is utilizing the brand product as the generic entity (DAW 5), or when there is no generic product in the marketplace (DAW Code 8).

191. There simply is no DAW Code for blocking the dispensing of an available generic drug in favor of a more expensive brand-name drug when generic substitution is mandated by State law.

I. Medicare Part D Claims for Unsubstituted Brand-Name Drugs Are Invalid Claims Under State Mandatory Generic Substitution Laws

1. State Pharmacy Laws Apply to Determine Whether a Medicare Part D Prescription Is “Valid”

192. All contracts between CMS and PDP Sponsors must include the requirement that the Sponsor agrees to comply with state law.¹¹⁸

193. Under the relevant Medicare Part D regulations,¹¹⁹ a “Valid Prescription” is a “prescription that complies with applicable state law requirements constituting a valid

¹¹⁸ 42 C.F.R. § 423.505(b)(15).

¹¹⁹ 42 C.F.R. §§ 423.100, 423.104(h).

prescription.” As such, the Part D regulations defer, “when applicable, to state law to determine whether a prescription is valid such that the prescribed drug may be eligible for Part D coverage.”¹²⁰

194. This means that “State law applies in determining what constitutes a valid prescription and that Part D benefits should be available only for otherwise covered drugs that are dispensed upon a valid prescription.”¹²¹

195. Medicare regulations thus explicitly incorporate state law to determine whether a prescription is valid. The validity of a prescription is a necessary condition precedent for a prescription to be reimbursable by Medicare. All contracts between CMS and PDP Sponsors must include the requirement that the Sponsor agrees to comply with state law.¹²²

196. The 2012 changes to Medicare Part D regulations reflect “CMS codification of longstanding policy merely specifies in regulation that applicable State law applies in determining whether a prescription is valid.”¹²³ This means that “State law applies in determining what constitutes a valid prescription and that Part D benefits should be available only for otherwise covered drugs that are dispensed upon a valid prescription.”¹²⁴

¹²⁰ *Medicare Program, Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes*, 77 Fed. Reg. 22072, 22152, 22159 (April 12, 2012), <https://www.govinfo.gov/content/pkg/FR-2012-04-12/pdf/2012-8071.pdf>. The 2012 changes to Medicare Part D regulations reflect “CMS codification of longstanding policy merely specifies in regulation that applicable State law applies in determining whether a prescription is valid.” *Id.* at 22139.

¹²¹ *Id.* at 22139.

¹²² 42 C.F.R. § 423.505(b)(15).

¹²³ *Id.* at 22139.

¹²⁴ *Id.*

197. It is the PDP Sponsor's obligation to ensure that its PBM and contracted network pharmacies are complying with the Part D requirement that prescriptions be valid under applicable state law.¹²⁵

198. Likewise, all pharmacies dispensing drugs to Medicare Part D beneficiaries remain subject to state pharmacy laws.¹²⁶

199. As part of their minimum pharmacy standards, seventeen States require that generic drugs must be substituted for brand-name drugs for all payors, including Medicare Part D, when the generic version of the brand-name drug is less costly for the beneficiary.¹²⁷

200. A PDP Sponsor (or its PBM) that submits PDE records to Medicare when it knows (or should have known) that the pharmacies in its network are not complying with the minimum pharmacy standards in that state, such as mandatory generic substitution laws, therefore has knowingly submitted (or caused to be submitted) false PDE records or statements which are untruthful, inaccurate and incomplete.

201. It is the PDP Sponsor's obligation to ensure that its PBM and contracted network pharmacies are complying with the Part D requirement that prescriptions be valid under applicable state law.¹²⁸

2. *Sponsors Must Require That Pharmacies Comply with State Mandatory Generic Substitution Laws*

202. Buying generic versions of prescription drugs instead of their brand-name equivalents can significantly reduce overall prescription drug costs across the health care system. Generics make up approximately 90% of all prescriptions, but they are only a fraction of overall

¹²⁵ *Id.*

¹²⁶ *Id.*

costs. Brand-name drugs make up the remaining 10%, but account for 79% of all drug spending. Furthermore, generic drugs have saved the U.S. health care system \$1.67 trillion from 2007 to 2016.¹²⁹

203. State law dictates whether a pharmacist may substitute a brand-name drug with a less expensive generic version when dispensing a prescription.

204. To increase access to generic drugs and reduce costs, state lawmakers have pursued allowing a pharmacist to make a generic drug substitution. Nearly every state allows pharmacists to substitute less costly generic drugs for brand-name drugs in certain circumstances.¹³⁰ In fact, as explained *infra*, many States have mandated substitution of less costly generic drugs instead of more expensive brand-name drugs.

205. Medicare Part D mandates that the PDP must require that pharmacies providing services comply with minimum standards for pharmacy practice as established by the States.

206. The standard pharmacy contracts such as those between SilverScript and the CVS Pharmacies require compliance with all state laws of the jurisdiction in which each prescription service was received, as well as regulations necessary to lawfully perform the duties required under the contract. Further, the contracts condition any payments thereunder upon the CVS Pharmacies'

¹²⁹ National Conference of State Legislatures, *Prescription Drug Resource Center, Generic Substitution Laws* (May 3, 2019), available at https://www.ncsl.org/portals/1/documents/health/Generic_Drug_Substitution_Laws_32193.pdf.

¹³⁰ See, e.g., Ariz. Rev. Stat. Ann. § 32-1963.01(A) ("If a medical practitioner prescribes a brand-name drug and does not indicate an intent to prevent substitution as prescribed in subsection E of this section, a pharmacist may fill the prescription with a generic equivalent drug."); Ohio Revised Code ORC § 4729.38 ("Unless instructed otherwise by the person receiving the drug pursuant to the prescription, a pharmacist filling a prescription for a drug prescribed by its brand-name may, subject to the following conditions, select a generically equivalent drug, or in the case of a drug that is a biological product, select an interchangeable biological product:").

compliance with such applicable Federal and State laws, rules and regulations.¹³¹

207. As part of their minimum pharmacy standards, seventeen States (hereinafter, the “States” or “State”) require that generic drugs must be substituted for brand-name drugs for all payors, including Medicare Part D, when the generic version of the brand-name drug is less costly for the beneficiary.¹³² These States’ laws mandating generic substitution constitute the minimum standards for pharmacy practice with which Medicare Part D requires compliance. The relevant State laws include¹³³:

	State	Citation
1.	Florida	Fla. Stat. § 465.025
2.	Hawaii	Haw. Rev. Stat. § 328-92
3.	Kentucky	KRS 217.822
4.	Maine	Me. Rev. Stat. Ann. Tit. 32, § 13781
5.	Maryland	Md. Code Ann., Health–Gen. § 15-118(a)
6.	Massachusetts	Mass. Gen. Laws ch. 112, § 12D
7.	Minnesota	Minn. Stat. § 151.21(3)
8.	Nevada	Nev. Rev. Stat. § 639.2583
9.	New Jersey	N.J. Stat. Ann. §24:6E-7
10.	New York	N.Y. Educ. Law §6816-a
11.	Pennsylvania	35 Pa. Cons. Stat. § 960.3
12.	Puerto Rico	P.R. Laws tit. 20, § 410b
13.	Rhode Island	R.I. Gen. Laws § 5-19.1-19
14.	Tennessee	Tenn. Code Ann. § 53-10-205
15.	Vermont	VT. Stat. Ann. Tit. 18, § 4605(a)
16.	West Virginia	W.Va. Code § 30-5-12b

¹³¹ 42 C.F.R. § 423.505(h)(15).

¹³² Even with mandatory substitution laws, all States allow prescribers to block pharmacist substitutions. Most involve the prescriber specifically prohibiting a substitution by stating that the brand-name drug is (medically) necessary for the patient. The prescriber must also use language such as “no substitution should be made”, “do not interchange” or “dispense as written/D.A.W.”

¹³³ Certain other states require substitution in particular instances. Michigan and Mississippi require generic substitution if the patient requests it. *See* MCL 333.17755; Miss. Code. Ann. § 72-21-117. Washington requires generic substitution, but only for biologics. *See* WI ST 450.13.

17.	Wisconsin	WI ST 450.13
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208. The failure to substitute generic drugs for more costly brand-name drugs, and the submission of (or causing the submission of) false PDE records or statements in support of claims for payment to the Medicare Part D program is a violation of the State laws mandating generic substitution.

209. All such unsubstituted claims so paid by PDP Sponsors like SilverScript were false as a result of unlawful conduct in refusing to require network pharmacies comply with State laws requiring mandatory substitution of generic drugs instead of costlier brand-name bioequivalent drugs.

210. PDP Sponsors must certify that the information submitted in their PDE records and statements is truthful and complies with Medicare Part D's requirements to follow State laws. By virtue of their Electronic Data Interchange Agreements with CMS, PDP Sponsors and their subcontractor PBMs also expressly certify, among other things, that the data they transmitted in the PDE was "accurate and complete" to their "best knowledge, information and belief."

211. A PDP Sponsor (or its PBM) that submits PDE records to Medicare when it knows (or should have known) that the pharmacies in its network are not complying with the minimum pharmacy standards in that State, such as mandatory generic substitution laws, knowingly has submitted (or caused to be submitted) false PDE records or statements which are untruthful, inaccurate and incomplete.

VI. CVS HEALTH HAS ENGAGED IN SYSTEMATIC DECEPTION AND ANTICOMPETITIVE CONDUCT

A. CVS Health's Compliance Program Was Inadequate to Prevent the SSG/DNS Scheme Fraud

212. At all times material hereto, CVS Health was obligated to (i) maintain a compliance

program to ensure the integrity of their payment data¹³⁴; (ii) annually attest to the accuracy and truthfulness of that data¹³⁵; and (iii) “comply with . . . Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law [and] the False Claims Act (31 USC §§ 3729 *et seq.*).”¹³⁶ The CVS Health compliance program must be effective in detecting, correcting, and preventing Medicare program noncompliance.¹³⁷

213. However, even after CVS Health entered into two (2) CIAs with the Office of Inspector General of the Department of Health and Human Services in 2014 and 2016, wherein it agreed to enhance its compliance programs, it nonetheless still included insufficient controls to prevent the SSG/DNS Scheme of deception and outright lies to Medicare and Part D beneficiaries as alleged herein.

214. However, as alleged herein, the CVS Health compliance program and its Code of Conduct were a sham. In reality, CVS Health has systematically, unethically and illegally conspired across its subsidiaries to deceive program beneficiaries and the Government through their SSG/DNS Scheme to deny access to less costly generic drugs.

215. Nor did CVS Health have sufficient controls in place to ensure that the CVS Pharmacies and non CVS Health-owned network pharmacies dispensed generic versions of the SSG/DNS Drugs as required in those States with mandatory generic substitution laws.

¹³⁴ 42 C.F.R. § 423.504(b)(4)(vi).

¹³⁵ 42 C.F.R. § 423.505(k).

¹³⁶ 42 C.F.R. § 423.

¹³⁷ 42 C.F.R. § 423.504(b)(4)(vi).

216. The CVS Health Executive Committee was made aware of the potential compliance risk the company faced by implementing the SSG/DNS Scheme, but determined that (comparatively) the risk was worth the substantial upside to the company, particularly since the company faced severe austerity financial measures related to the delay in completing the Aetna acquisition.

217. Likewise, numerous senior executives within CVS Health senior management (including the Relator) complained that this was highly unethical, and pointed out that this was in clear violation of its Code of Conduct. Moreover, they were afraid that CVS Health pharmacists in charge of Medicare Part D coverage determinations would call the CVS Health “Ethics Line” over fears that they could lose their licenses because they were being asked to deceive beneficiaries.

218. Illustrating that any compliance concerns raised would have fallen on deaf ears, the SSG/DNS Scheme had the explicit blessing of Patrick Jeswald, SilverScript Compliance Officer from 2013 through 2018 and current CVS Health Chief Compliance Officer, Medicare. For example, when Suboxone Film was added to the SSG/DNS Scheme, on March 5, 2019 Bethany Crotts (Clinical Advisor, Medicare Part D) emailed Jeswald to confirm whether he had any concern regarding the implementation of a block which would prevent SilverScript beneficiaries from receiving the Suboxone Film generic. Jeswald responded the same day: “No concerns.”

219. Instead of “Doing the Right Thing,” as had been promised in its Code of Conduct, CVS Health and its subsidiaries have conspired together to engage in a systematic scheme of dishonest and unethical behavior (a) to violate its obligation under the FTC Consent Order that it would not, directly or indirectly, make deceptive claims about the price or cost of Medicare Part D prescription drugs; (b) to violate its obligation under the Federal antitrust laws not to share

competitively sensitive information between its firewalled subsidiaries, which conduct was aimed at increasing the cost of the SSG/DNS Drugs, thereby harming elderly, ESRD and disabled SilverScript beneficiaries; (c) to mislead and deceive Medicare Part D beneficiaries; (d) to submit false PDE records and statements in support of Medicare Part D claims which it knew were untruthful, inaccurate and incomplete; (e) to refuse to dispense less costly generic drugs in those States requiring mandatory generic substitution; and (f) to submit PDE data that was inaccurate, incomplete and untruthful and thereby made false attestations about compliance with the law.

B. CVS Health Deceived SilverScript Beneficiaries

220. CMS encourages Part D sponsors to submit formularies similar to those in widespread use in the market. CMS will check the formulary to ensure inclusion of a range of drugs in a broad distribution of therapeutic categories and classes, in order to satisfy the Medicare Modernization Act (MMA) requirement that a sponsor's categorization system does not substantially discourage enrollment by any group of beneficiaries.¹³⁸ CMS will consider the specific drugs, tiering and utilization management strategies employed in each formulary, and will identify outliers from common benefit management practices for further evaluation. Sponsors may be asked to provide written clinical justification for unusual benefit features that are identified as outliers.¹³⁹

221. A PDP Sponsor such as SilverScript cannot lie to, mislead, or keep critical information from its beneficiaries to induce them to select a SilverScript plan, nor engage in deception about the availability of less costly, identical authorized generics after the beneficiary has enrolled in the plan. This is especially true when doing so results in elderly, ESRD and disabled

¹³⁸ Prescription Drug Benefit Manual Chapter 6, Section 30.2.

¹³⁹ *Id.*

populations not being able to obtain their needed medication.

1. SilverScript Failed to Provide Information Regarding the SSG/DNS Scheme to Prospective Part D Beneficiaries

222. So that beneficiaries can make informed choices in selecting a Part D plan, under 42 § 423.128(b)(2)(iii), CMS required SilverScript to provide accurate information regarding cost-sharing (such as copayments, deductibles, and coinsurance). Section 423.128(b)(2)(iv) also required SilverScript to provide any other conditions associated with receipt or use of benefits. And, section 423.48 required SilverScript to provide information to allow “current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage.”

223. Those disclosures did not happen here. To the extent that elderly, ESRD or disabled beneficiaries would have investigated further, at no time would the SSG/DNS Scheme have been disclosed in the SilverScript enrollment materials. For example, nowhere does the SilverScript formulary ever explain to potential members that *some of the time*, instead of making less costly, identical authorized generics the formulary choice, SilverScript would instead require them to pay higher costs for the brand-name product. Instead, the formulary only discloses that SilverScript would from time to time substitute the lower-cost generic drug, not the other way around.¹⁴⁰ This is discriminatory and violates the obligation that Part D plans “must offer the Part D benefit uniformly within the plan’s service area including any segments.”¹⁴¹

224. Truthful, accurate information about the SilverScript formularies was necessary for beneficiaries to make “informed decisions” about their coverage and plan choice. Yet, for any

¹⁴⁰ SilverScript Choice (PDP) 2020 Formulary (List of Covered Drugs), at i, https://www.silverscript.com/pdf/Form_2020_CHOICE_EN.pdf

¹⁴¹ CMS, Reinterpretation of the Uniformity Requirement (April 27, 2018).

beneficiary who needed one of the SSG/DNS Drugs, SilverScript did not inform them that their cost share would be higher than if the identical authorized generics were available or that the cash price would often be less costly than the on-formulary SSG/DNS Drugs. SilverScript also did not disclose that, as a result of its games, the SSG/DNS Scheme would force them into the Donut Hole and the Catastrophic Coverage stages faster, nor that the Government's costs would increase dramatically.

225. A recent Drug Channels article demonstrates how PDPs' gaming of the pricing of brand-name drugs induces beneficiaries with the promise of lower premiums. In Adam J. Fein's January 22, 2020 Drug Channels article entitled "Why Part D Plans Prefer High List Price Drugs That Raise Costs for Seniors,"¹⁴² Fein illustrates that, despite drug manufacturers offering authorized generic products with lower list prices, Medicare Part D plans were rejecting the therapeutically identical and lower-priced authorized generic versions of these drugs. That decision significantly affects seniors' out-of-pocket costs because "Part D plans are needlessly costing many of them thousands of dollars." This practice also results in the Government's Medicare spending being "unnecessarily higher."¹⁴³

226. Especially relevant here, Fein highlights the pricing for Gilead's two hepatitis C drugs, Harvoni and Epclusa, as well as the pricing for their identical authorized generics.¹⁴⁴ The article explains that the less costly authorized generic drugs are not being included on Medicare Part D formularies. According to Fein, the result has a significant impact for beneficiaries' cost

¹⁴² Adam Fein, *Why Part D Plans Prefer High List Price Drugs That Raise Costs for Seniors*, Drug Channels (Jan. 22, 2020), <https://www.drugchannels.net/2020/01/why-part-d-plans-prefer-high-list-price.html>.

¹⁴³ *Id.*

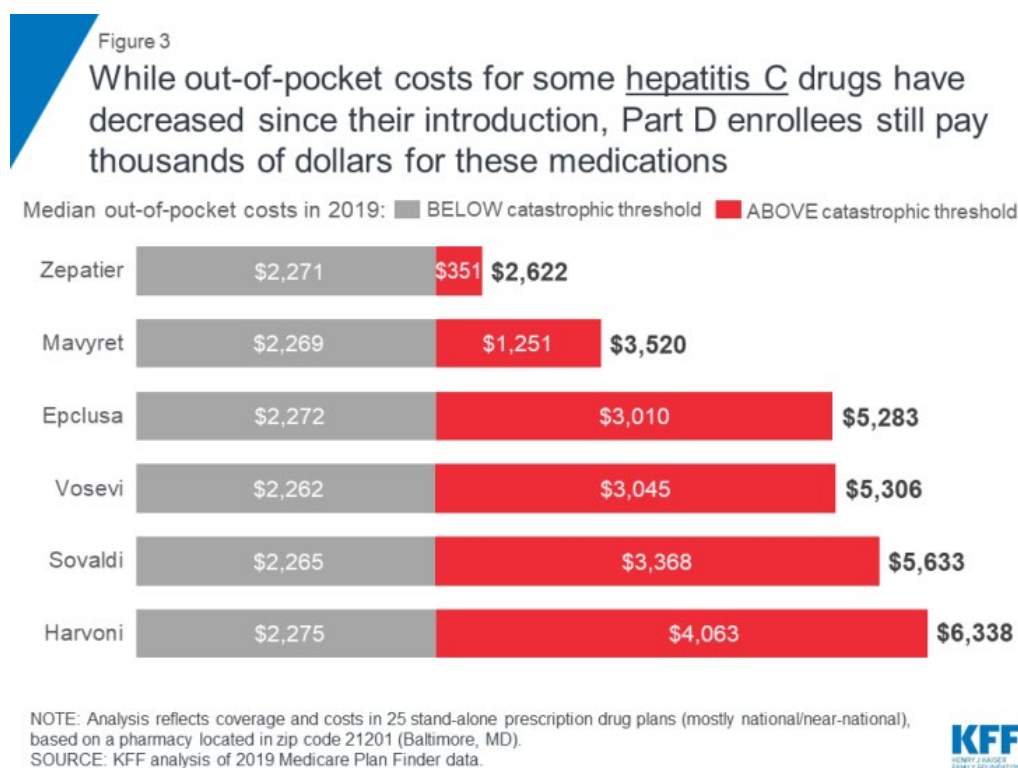
for these drugs since they are pushed into the catastrophic phase sooner where their additional costs may be substantial:

Medicare beneficiaries, unlike those in most private insurance plans, can face unlimited out-of-pocket prescription drug costs if they reach the catastrophic coverage limit. Medicare covers 80% of the cost in the catastrophic phase, while plans pay 15% and the beneficiary pays 5% coinsurance.

Progression through the Part D benefit tiers is based on the prescription price negotiated between the plan and the pharmacy. That negotiated price excludes rebates, so beneficiaries reach catastrophic coverage—and its unbounded 5% out-of-pocket expense—sooner when using products with higher list prices.

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227. Here is a chart Fein shares to illustrate the dramatically increased costs for beneficiaries:



¹⁴⁵ Fein article (emphasis added).

228. According to Fein’s calculations, a Part D beneficiary’s median out-of-pocket costs for brand-name Epclusa were \$5,283 and \$6,338 for brand-name Harvoni. By comparison, if the less costly and identical authorized generics had been dispensed instead, he estimates that the out-of-pocket costs would be about \$3,300.¹⁴⁶

229. As it was required to do under the CVS Caremark deal with Gilead, SilverScript has systematically preferred the SSG/DNS Drugs like Harvoni and Epclusa with higher list prices than the identical authorized generics. Requiring them to use expensive drug products like Harvoni and Epclusa pushes more beneficiaries into the Catastrophic Coverage Stage, where the plan liability is low, but where Medicare and beneficiary liability could be substantial.

230. Fein describes the scheme as “gaming” which they use to reduce premiums, enabling them to sign up more Part D enrollees on their plans: “Here’s the twist: Plans can use the additional rebates earned from the high-list price products to reduce monthly premiums and *grab more Part D market share*. The weird math of Part D bidding and its benefit structure encourage this gaming.”¹⁴⁷

231. Illustrating how pernicious the Scheme is, it allowed CVS Health to collect more rebates from the Drug Makers, allowing SilverScript to reduce premiums and actually enabling SilverScript to sign up even more LIS beneficiaries through automatic enrollment.

232. There were an estimated 13 million Part D LIS enrollees in 2021. Beneficiaries who are LIS qualify for the additional assistance, and CMS automatically enrolls them into PDPs with premiums at or below the regional average (the LIS “Benchmark”) if they do not choose a plan on

¹⁴⁶ *Id.*

¹⁴⁷ *Id.* (emphasis added).

their own.¹⁴⁸

233. To qualify as a Benchmark plan, the PDP premium must be at or below the regional benchmark premium, calculated based on an enrollment-weighted average of the monthly premiums between all PDPs offered in the region. LIS beneficiaries are automatically and randomly assigned evenly between regional Benchmark plans.¹⁴⁹

234. Since its exit from the CMS sanctions on December 20, 2013, SilverScript has relied heavily on auto-enrolling LIS beneficiaries for its growth. Much of its growth was fueled by the SSG/DNS Scheme with the Drug Makers to block less costly generics on its formularies.

2. SilverScript's Marketing Materials Were Materially Misleading and Deceptive

235. The accuracy, completeness and truthfulness of marketing materials used by Part D Sponsors, allowing beneficiaries to choose and enroll with a particular Part D Sponsor, is very important for both the Part D beneficiary and the Medicare Part D Program because Part D beneficiaries are encouraged to choose a plan based on representations which will directly affect the coverage Medicare Part D will provide.

236. However, for the SSG/DNS Scheme to succeed, the deals CVS Caremark had entered into required SilverScript to engage in systematic lies and deceit, starting with its representations to potential beneficiaries evaluating what PDP to choose and continuing through the administration of the plan. Throughout its solicitation materials provided to prospective Part D

¹⁴⁸ Kaiser Family Foundation, *An Overview of the Medicare Part D Prescription Drug Benefit* (Oct. 13, 2021), available at <https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/>.

¹⁴⁹ Rajul Patel, Mark Alberg, Joseph Woelfel, Michelle Amaral, Paresh Varu, *Medicare Part D Roulette: Potential Implications of Random Assignment and Plan Restrictions*, 3 Medicare & Medicaid Research Review E1, E2 (2013).

beneficiaries, SilverScript uses a bait-and-switch scheme to emphasize it is “All about you,” deceptively telling elderly, ESRD and disabled prospective members that it will *always* act *only* on behalf of beneficiaries and not in its own self-interest. Indeed, its marketing materials to prospective enrollees show happy seniors hiking through the woods, telling them it has “one focus”: “to deliver Medicare prescription drug coverage that works well *every day, in every way*”¹⁵⁰.



237. As part of the sales pitch, SilverScript touts its expertise with Medicare Part D as a reason beneficiaries should trust it to be honest: “We specialize in Medicare Part D — so you don’t have to.”¹⁵¹

¹⁵⁰ SilverScript 2020 Plan Decision Guide Your guide to choosing a Medicare Part D plan, at I (emphasis added), <https://www.silverscript.com/pdf/2020-plan-and-enrollment-guide.pdf>

¹⁵¹ *Id.* at 3.

238. The message was that beneficiaries could trust SilverScript. One marketing piece states that SilverScript is “[a]ll about quality, reliability and trust” and that “[m]illions of Medicare beneficiaries choose SilverScript for the coverage, copays . . . and customer care.”¹⁵²

All about quality, reliability and trust.

Millions of Medicare beneficiaries choose SilverScript year after year for the coverage, copays, convenience and customer care.

This trust in SilverScript was misplaced. In reality, once beneficiaries were enrolled, SilverScript would not only block access to the generics of the SSG/DNS Drugs, it would mislead them about their price or cost.

239. The SilverScript “Brand Promise”¹⁵³ to every Part D beneficiary emphasizes “**confidence**,” “**comfort**,” and “**consistency**.” Beneficiaries were told SilverScript provided them with “trust and **peace of mind** that they have chosen the right plan that **cares** for them.” Not only that, but the Brand Promise was that, “[w]ith SilverScript, every prescription is more than a mere transaction; each is a commitment to demonstrate our expertise and sole focus on delivering Part D coverage that helps keep participants on their path to better health.”

¹⁵² SilverScript 2019 Plan Decision Guide.

¹⁵³ See SilverScript 2016 Plan Year Preview, <http://kafl.com/wp-content/uploads/2015/11/2016cvssilverscriptsneakpeakallstates.pdf>.

SilverScript Brand Promise



For Medicare Part D beneficiaries, we offer **confidence** over confusion and **comfort** that comes with **consistency**. With SilverScript, every prescription is more than a mere transaction; each is a **commitment** to demonstrate our **expertise** and sole focus on **delivering** Part D coverage that helps keep participants on their path to better health.

We've been here since Medicare Part D began in 2006, and we focus 100 percent on delivering prescription drug coverage that works well in every way, every day. We go the extra mile to educate, explain and **empathize** and provide Part D beneficiaries with trust and **peace of mind** that they have chosen the right plan that **cares** for them.

What the Brand Promise does not mention is that SilverScript “trust and peace of mind” only went so far. Often, when it was in CVS Health’s financial interest, rather than having as its “sole focus” keeping beneficiaries on “their path to better health” through access to less costly (and identical) generic drugs, CVS Health looked to its own profit instead.

240. It used the lure of low premium costs, telling prospective customers: “SilverScript plans are affordable and comprehensive.”¹⁵⁴

241. One SilverScript online direct ad shows an actor portraying a flyfisherman and tells viewers it will help prospective elderly, ESRD and disabled members “save money”:

¹⁵⁴ *Id.* at 11.



242. The SilverScript marketing materials have also told prospective enrollees that using a SilverScript plan will help them “cover the cost” of their expensive prescription drugs: “Prescription drugs can be expensive. Our plans can help you cover the cost.”¹⁵⁵ And in another marketing piece, it tells customers they should choose SilverScript because it will “protect your health savings” through “lower premiums” and “competitive costs.”¹⁵⁶

243. These claims are materially inaccurate. If it were being honest, what SilverScript should have said is that it “[h]elps you save money *only some of the time*.” Sadly, for the SSG/DNS Drugs, SilverScript did not help defrauded beneficiaries at all, instead forcing them to take much costlier brand-name drugs. Rather than giving them the “peace of mind” about their Medicare Part D plan that they were promised, for any elderly, ESRD or disabled beneficiaries seeking less costly versions of the SSG/DNS Drugs, its message was, as one 82-year-old woman living in Florida put it when she was told she could not access the less costly Asacol HD, “tough luck.”

244. Nowhere in the promises made in its glossy marketing materials does SilverScript disclose that for many beneficiaries its SSG/DNS formulary choices would actually drive their

¹⁵⁵ *Id.* at 6.

¹⁵⁶ Why Choose SilverScript (PDP)?, <https://www.silverscript.com/learn/why-choose-silverscript>

costs into the Donut Hole and Catastrophic Coverage Stages much sooner, nor that these decisions would dramatically increase both their cost, but also the Government's cost sharing.

245. What SilverScript failed to disclose are the warped incentives baked into its formularies, which allowed it to offer lower premiums to grab more market share of Part D customers. The SSG/DNS Scheme thus has forced many beneficiaries to face potentially substantial out-of-pocket prescription drug costs as well as dramatically increasing the Government's costs.

246. Its marketing materials fail to disclose that, for SilverScript elderly, ESRD and disabled members seeking access to lower the cost of extremely expensive drugs like Harvoni, Epclusa, their efforts were doomed from the start because CVS Health had already made the decision at the highest levels of the company that SilverScript would deny all formulary exceptions. Not only that, if they got their medications from a CVS Pharmacy, they would soon find that the less costly authorized generics were not even being stocked on their shelves.

247. Beneficiaries' Medicare rights were denied *in every instance* when SilverScript automatically denied formulary exceptions for less costly, lifesaving drugs they needed. Likewise, the SilverScript (through its PBM CVS Caremark and the CVS Pharmacies) violated the obligation to "offer the Part D benefit uniformly"¹⁵⁷ *in every instance* when beneficiaries were unable to receive the less costly generics because the CVS Pharmacies were not stocking these drugs. These beneficiaries were thereby deceived about the benefits offered under the SilverScript plan. By not disclosing this information, CVS Health and its subsidiaries violated the terms of the 2012 FTC Consent Order because beneficiaries were being provided with deceptive information about their

¹⁵⁷ CMS, Reinterpretation of the Uniformity Requirement (April 27, 2018).

SilverScript coverage options.

248. These claims are in explicit violation of Medicare directives that Plan Sponsors “are prohibited from distributing communications that are materially inaccurate, misleading, or otherwise make representations or could confuse beneficiaries.”¹⁵⁸ Plan Sponsors “may not” “[u]se unsubstantiated absolute or qualified superlatives”¹⁵⁹

249. Not only has SilverScript engaged in a bad faith bait-and-switch scheme to induce beneficiaries to select its plans, once they were enrolled, it has routinely lied to them about the cost and availability of the SSG/DNS Drugs in order to prevent them from getting less costly, identical alternatives – *i.e.*, before the PDE is ever submitted. In doing so, as alleged herein, SilverScript has thereafter (a) violated State mandatory substitution laws and/or (b) created false PDE claim records which included false DAW coding (*see* discussion below). These misrepresentations and lies to beneficiaries have violated numerous laws and regulations.

C. In Order to Carry Out Its Illicit SSG/DNS Scheme, CVS Health Violated Its 2007 Firewall Agreement and the Terms of the 2012 FTC Consent Order

1. CVS Health and Its Subsidiaries Breached the 2007 Firewall

250. As a part of its 2007 agreement with the FTC, the merged entity would maintain “stringent firewall protections between [its] CVS Pharmacy retail business and [its] CVS

¹⁵⁸ Medicare Communications and Marketing Guidelines (MCMG), section 30.7 (July 20, 2018), at 6.

¹⁵⁹ *Id.*

Caremark PBM business to prevent any anti-competitive activity.”¹⁶⁰ For example, in its Code of Conduct, CVS Health claims that it “maintains firewalls between select businesses within the Company to separate and protect certain competitively sensitive information that each business possesses.”¹⁶¹ One of the main reasons for requiring a firewall between these subsidiaries is to prevent the very type of illegal activity being complained of herein.

251. With regard to sharing of sensitive competitive information between SilverScript and CVS Caremark specifically, CVS Health in 2018 told one Insurance Department that its long-standing “firewall policy prevents SilverScript employees from accessing competitively sensitive information Caremark has collected from health plans that compete with SilverScript in the Medicare Part D area. There are robust compliance protocols in place at CVS Health to prevent

¹⁶⁰ See Press Release, *CVS Health Statement on PA Auditor General’s Report on PBMs* (Dec. 11, 2018), available at <https://cvshealth.com/newsroom/press-releases/cvs-health-statement-on-pa-auditor-generals-report-on-pbms>; see Press Release, *CVS Health Statement on Ohio Auditor of the State’s Report on Pharmacy Benefit Managers* (Aug. 16, 2018) (“CVS Health maintains stringent firewall protections between our CVS Pharmacy retail business and our CVS Caremark PBM business to prevent any anti-competitive activity by either side of our enterprise”), available at <https://cvshealth.com/newsroom/press-releases/cvs-health-statement-on-ohio-auditor-of-the-states-report>. Moreover, at least one insurance department has ordered CVS Health to maintain a strict firewall policy. See Order of the Insurance Commissioner of the Commonwealth of Pennsylvania, Order No. ID-RC-18-14 (CVS Health ordered to “develop, implement, monitor the operation of and enforce strict compliance with a firewall policy that is applicable to the Domestic Insurers.”).

¹⁶¹ CVS Health Code of Conduct (November 2019) (“Such information includes contract terms, pricing and other financial arrangements. These firewalls become important in contract negotiations, in which the businesses must compete on the same terms as their competitors.”), available at <https://cvshealth.com/sites/default/files/cvs-health-code-of-conduct.pdf>

any improper exchanges of information across its business units.”¹⁶²

252. On June 4, 2018, Melissa Schulman, CVS Health Senior Vice President, Government Relations, testified at a hearing before the New York Standing Committees on Insurance and Health, assuring that CVS Health maintains a “firewall around business sensitive information and so the decision of the folks who look at pharmacy purchasing would have had no [insight] into the business information as to what was happening with the reimbursement on the Caremark side.”¹⁶³ Schulman reassured the Committees that the firewall had been part of its promise to the FTC in 2007 at the time of the merger between CVS and Caremark, as well as part of its Code of Conduct:

It’s part of a commitment that we made to the FTC when CVS and Caremark came together. It is part of our code of conduct. It is part of our training. That’s where that’s what that’s based in. There are also computer safeguards that information is not inappropriately shared when it comes to business sensitive information as well. There’s additional training. There are essentially waiting periods so people can’t be employed in one side and then be employed in the other without essentially a cleansing period. We have a number of procedures around this.¹⁶⁴

253. When questioned whether firewalls would ever prevent “all those components from working together to maximize the power and profit of CVS [Health],” Schulman swore that

¹⁶² CVS Health Form A, *Statement Regarding The Acquisition Of Control Of Or Merger With A Domestic Insurer Aetna Life Insurance Company, Aetna Insurance Company Of Connecticut, Aetna Health And Life Insurance Company, Aetna Health Inc. (A Connecticut Corporation) And Aetna Better Health Inc. (A Connecticut Corporation) Subsidiaries Of Aetna Inc.*, Connecticut Insurance Department (Amended Aug. 13, 2018), available at <https://www.cidverifylicense.ct.gov/portalApps/viewFile.aspx?F=435>.

¹⁶³ See also Testimony of Melissa A. Schulman, CVS Health Senior Vice President, Government Relations before the New York State Assembly Standing Committees On Insurance and Health Public Hearing CVS Health’s Acquisition of Aetna Inc. (June 4, 2018), at 106, available at https://nystateassembly.granicus.com/DocumentViewer.php?file=nystateassembly_169e83e0d600bff7e5d3d9e8ad6f1e98.pdf&view=1.

¹⁶⁴ *Id.* at 107.

“[t]here are, there will be and there are protections around that.”¹⁶⁵

254. Schulman’s pledge was demonstrably false even then. The firewall protections allegedly in place had already failed to prevent CVS Health from conspiring across its three wholly owned and vertically integrated subsidiaries to engage in the illegal SSG/DNS Scheme with the Drug Makers to block competition from less costly generic drugs. In fact, as alleged herein, the SSG/DNS Scheme was only made possible because the parent corporation CVS Health owned and controlled the Medicare PDP (SilverScript), the PBM that administers the pharmacy benefit on behalf of SilverScript as the Plan (CVS Caremark), and the retail, mail order, and specialty pharmacies that dispense the SSG/DNS Drugs (CVS Pharmacies).

2. CVS Health and Its Subsidiaries Violated the 2012 Consent Order

255. CVS Health’s use of its position in the market to mislead and deceive has been the focus of enforcement actions and government concern since the consolidation of the various CVS Health entities in 2007. For example, CVS Caremark in 2008 entered into a \$41 million settlement and Consent Decree with 28 state Attorneys General with regard to its deceptive drug substitution business practices.¹⁶⁶

256. Again in 2009, two years after the merger, CVS Caremark’s conduct caught the attention of health plans, independent pharmacists, and consumer groups, along with five U.S. Senators and over a dozen members of the House of Representatives, who asked the FTC to investigate the potential anti-competitive effects of the merged retail-PBM business model and

¹⁶⁵ *Id.* at 108.

¹⁶⁶ See, e.g., Washington State Office of Attorney General, *Attorney General McKenna Announces Caremark to Pay \$41 Million to Resolve Multistate Consumer Protection Claims* (Feb. 14, 2008), <https://www.atg.wa.gov/news/news-releases/attorney-general-mckenna-announces-caremark-pay-41-million-resolve-multistate>.

evaluate the potential risks for consumers and health plans when such a large portion of the pharmaceutical supply chain was controlled by one company.¹⁶⁷ Among the concerns raised was that the combination of a PBM and a retail pharmacy posed an inherent conflict of interest which would harm consumers.

257. According to Change to Win, a partnership of six million union members:

As a PBM, CVS Caremark is expected to save health plans money by negotiating lower drug prices with manufacturers and by promoting lower-cost drugs to participants, while ensuring that plan participants have access to medicine in a broad pharmacy network. As a retailer, CVS Pharmacy has an incentive to drive plan participants into its stores so it can fill the maximum number of prescriptions, particularly those with high markups, and has little incentive to help save health plans money.¹⁶⁸

258. The concerns raised led to a three-year FTC investigation into whether CVS Caremark was gaming its position as owner of a PBM and retail pharmacy to increase the cost of drugs to its members.”¹⁶⁹

259. At the conclusion of its investigation, the FTC levied penalties against CVS for its

¹⁶⁷ Reed Abelson, Natasha Singer, *5 Groups Call for the Breakup of CVS Caremark: Pressure Grows to Unwind CVS Merger*, New York Times (April 24, 2011) (“CVS Caremark has been accused by consumer advocates of not fulfilling promises made at the time of the merger; executives said then they would erect a firewall between the CVS and Caremark businesses and would be agnostic about where consumers filled their prescriptions.”); *Providence Business Journal*, *FTC competition unit to examine CVS* (June 24, 2009), <http://www.pbn.com/detail/43167.html>. Letters to the Federal Trade Commission calling for a review of the CVS Caremark merger came from more than 17 members of Congress, six health plans and purchasing coalitions, and three consumer groups.

¹⁶⁸ CVS Caremark: An Alarming Merger, Two Years Later – How the CVS-Caremark merger increases health plan costs, creates obstacles to oversight, and threatens patient privacy (Nov. 2009), [liye.info-cvs-caremark-prescription-drug-discounts-pr_13fed139fc3c7b9073a110d8f2b83c3a\(1\).pdf](http://liye.info-cvs-caremark-prescription-drug-discounts-pr_13fed139fc3c7b9073a110d8f2b83c3a(1).pdf).

¹⁶⁹ *Id.* at 3 (“Now, in addition to collecting the health plan’s payment for an expensive brand-name drug, Caremark may be able to manipulate the reimbursement rate to CVS Pharmacy in order to collect a higher profit.”)

conduct. On January 3, 2012, as part of closing its investigation, the FTC entered into a settlement and consent order with CVS, which admitted liability and agreed to pay \$5 million to resolve allegations that it had lied about the pricing of drugs to induce beneficiaries to select Medicare Part D coverage from its subsidiary RxAmerica. As the FTC explained in its press release announcing the settlement:

In January 2012, the FTC had charged that CVS Caremark misrepresented the prices of certain Medicare Part D prescription drugs – including drugs used to treat breast cancer symptoms and epilepsy – at CVS and Walgreens pharmacies. The claims caused many seniors and disabled consumers to pay significantly more for their drugs than they expected and pushed them into the “donut hole” – a term referring to the coverage gap where none of their drug costs are reimbursed – sooner than they anticipated or planned. The settlement barred the deceptive claims and required CVS Caremark to pay \$5 million to reimburse affected Medicare Part D consumers for the price discrepancy.¹⁷⁰

260. In the January 2012 FTC Complaint against CVS, it alleged that CVS as a matter of company policy had misrepresented, both expressly and by implication, its Medicare Part D pricing to beneficiaries.¹⁷¹

261. In the Agreement and Consent Order which issued on the same day, CVS agreed for a period of twenty (20) years¹⁷² that it would not “misrepresent, in any manner, or assist others in misrepresenting, in any manner, directly or indirectly, expressly or by implication, the prices or costs associated with Medicare Part D prescription drug plans.”:

IT IS ORDERED that Respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and those persons in

¹⁷⁰ Press Release, <https://www.ftc.gov/news-events/press-releases/2012/09/ftc-return-money-victims-allegedly-deceptive-drug-price-claims>.

¹⁷¹ FTC Complaint, *In the Matter of CVS Caremark Corporation*, Dkt. No. C-4357, ¶¶ 7, 11-16, 17, 18.

¹⁷² FTC Agreement Containing Consent Order, *In the Matter of CVS Caremark Corporation*, File No: 112 3210, at Section VIII, p. 8.

active concert or participation with them who receive actual notice of this order by personal service or otherwise, in connection with the marketing, advertising, promotion, distribution, offer for sale, sale or administration of Medicare Part D prescription drugs and Medicare Part D prescription drug plans, in or affecting commerce, **shall not misrepresent, or assist others in misrepresenting, in any manner, expressly or by implication, the price or cost of Medicare Part D prescription drugs or other prices or costs associated with Medicare Part D prescription drug plans.**¹⁷³

262. At the time, in response to a question from the District of Columbia Attorney General about what would happen if CVS violated the terms of the Consent Order, the FTC explained that “to the extent that [CVS Health] and/or any of its subsidiaries . . . violates the terms of the Commission’s final order, such as by misrepresenting the price or cost of Medicare Part D prescription drugs, it would be liable for civil monetary penalties of up to \$16,000 per violation, pursuant to Section 5(l) of the FTC Act.”¹⁷⁴

263. Yet, despite this clear prohibition and the potential liability the Company faced, CVS Health’s Executive Committee has used its position across the vertically integrated enterprise to coordinate the SSG/DNS Scheme, once again misleading beneficiaries “expressly or by implication” about the prices or costs (in addition to access) of the SilverScript plan. And what has enabled CVS Health to mislead beneficiaries has been its improper and illegal sharing of sensitive competitive information between the CVS Health entities.

3. The SSG/DNS Scheme Was Only Possible Because of Anticompetitive Conduct by CVS Health and Its Subsidiaries

264. The typical arms-length structure between vertical competitors would have normally provided a competitive check and balance against the corrupt behaviors in the SSG/DNS Scheme. For example, pharmacies would ordinarily be incentivized to dispense generic drugs,

¹⁷³ *Id.* at Section I, p. 3 (emphasis added).

¹⁷⁴ FTC Letter to the Honorable Irvin B. Nathan, Attorney General for the District of Columbia (May 3, 2012).

rather than brand-name drugs, because the reimbursement is greater for the pharmacies on the generics and, because the cost to the pharmacy customers is lower for generics, customer satisfaction is higher. But under the SSG/DNS Scheme, even though some components of the business, like the CVS Pharmacies, would lose money (by not stocking the more profitable authorized generic drugs) or face potential compliance scrutiny, the vast profits to be made by CVS Health through the CVS Caremark rebate deals outweighed those concerns.

265. The SSG/DNS Scheme worked because the highest levels of CVS Health leadership had determined that it provided what they euphemistically called an “enterprise-wide benefit” despite some in senior management (including the Relator) complaining that it was “highly unethical.”

266. Generally, there would be compelling commercial incentives on the part of vertically-integrated firms like CVS Health to ensure the confidentiality of their customers’ or suppliers’ competitively-sensitive information. Losing the trust of, and potentially the commercial relationships with, its customers or suppliers of one business unit within an enterprise in order to gain competitive advantage for another unit would in most circumstances have been economic suicide for CVS Health. In this instance, in order to reduce the risk of customer pushback, beginning in 2019, CVS Health made the calculated business decision not to deploy its Scheme with its employer customers contracting with CVS Caremark (where it might face considerable member complaints) and instead would begin restricting the illegal SSG/DNS Scheme only to its SilverScript Medicare Part D business (because it viewed the Government as not actively monitoring its conduct).

267. CVS Health management thus concluded the minimal risk of being caught by the Government was worth the upside profits it would reap from its PDP Sponsor (SilverScript)

coordinating with the CVS Pharmacies and PBM CVS Caremark to prevent beneficiaries from having access to less costly generic drugs. Moreover, the profits the enterprise hoped to pocket would make up for any financial losses any subsidiary would suffer – even if its conduct was not only a money-loser, but potentially illegal.

268. Meanwhile, in order to blunt any potential scrutiny, CVS Health has publicly insisted it designs “formularies that encourage the use of generics and biosimilars, and [created] new tools to help bring escalating drug prices under control.”

269. CVS Health Executive VP and CVS Caremark President Derica Rice even maintained in a 2019 article posted on the CVS Health website that the company used its “proven” strategies to control the cost of expensive drugs like Harvoni even after Gilead had introduced authorized generic copies of these extremely expensive Hep C drugs. Rice proclaimed that the CVS Caremark deals with Gilead and other SSG Drug makers would help its customers because it had “been able to use our proven cost management strategies and negotiated with manufacturers to help ensure plan members had access to appropriate therapies while clients could focus on controlling plan costs.”¹⁷⁵

270. These were lies meant to deflect attention from its illegal conduct. What Rice failed to mention is that the “proven cost management strategies” CVS Health had used for Harvoni and the other SSG/DNS Drugs did not provide “access” to the less costly authorized generic versions for elderly, ESRD, and disabled SilverScript members. Instead, covertly, the CVS Health leadership had taken advantage of its enterprise-wide control of CVS Caremark, SilverScript and

¹⁷⁵ Derica Rice, *Why the Time is Right for a New Pricing Model: As Market Trends Evolve, Payors Need an Adaptable Approach* (March 19, 2019), <https://payorsolutions.cvshealth.com/insights/why-the-time-is-right-for-a-new-pricing-model>.

the CVS pharmacies to garner huge profits for itself by making the more expensive brand-name Harvoni and the other SSG/DNS Drugs the only SilverScript formulary options, thus driving beneficiaries' costs much faster into the Donut Hole and Catastrophic Coverage Stages.

271. Likewise, CVS Health management knew that in seventeen states its pharmacies must dispense the generic versions of drugs according to State mandatory generic substitution laws. Yet, the CVS Health Executive Committee made the deliberate decision that CVS Caremark would require its CVS Pharmacies to dispense the brand-name drugs instead of the less costly authorized generics. In doing so, the Executive Committee knew this would be at the expense of beneficiaries and Medicare, and would be in violation of State mandatory generic substitution laws.

272. The Scheme would not have been possible had the CVS entities (CVS Caremark, SilverScript, and the CVS pharmacies) been truly operating at arm's length as they had promised repeatedly since the 2007 merger. If they had operated at arm's length, the CVS subsidiaries would have ensured that each entity's business objectives, financial goals, pricing, and compensation would not be connected with the performance of the firewalled organization.

273. Through its breaches of the firewalls, CVS Health has facilitated coordinated collusive activities between its subsidiaries and the SSG/DNS Drug Makers, which harmed Part D beneficiary access to less costly generic drugs.

274. CVS Health's unified control over the vertically integrated enterprise has thus ensured that the fraudulent scheme could be successful because it viewed the risk of being caught was worth the significant profits it would garner. So, even though the fraudulent scheme violated its promised firewalls and the FTC Consent Order, as well as State laws requiring pharmacies to substitute generic medications for the costlier brand-name versions, because CVS Health owned

and therefore controlled the CVS Caremark PBM, the SilverScript PDP, and the CVS Pharmacies, any potential discord between what it wanted (dispensing of more expensive brand-name SSG/DNS Drugs) and what the law required could be easily swept aside.

275. Had the CVS Health entities been truly operating behind a firewall, they would have been unable to carry out the SSG/DNS Scheme. Because it would have been administering the Medicare Part D benefit in the best interests of its beneficiaries (instead of the interests of its corporate parent CVS Health), PDP Sponsor SilverScript would have had operated a robust and effective compliance program which would have ensured that beneficiaries had access to a full and fair grievance and coverage determinations process, and were fully informed of less costly generic options that should have been available to them.

276. Likewise, had the firewall restricted access to business sensitive information, SilverScript would have (a) required the CVS Pharmacies and non-CVS Health owned network pharmacies disclose to beneficiaries accurate differential prices available for less costly (often identical) generic drugs; (b) required the CVS Pharmacies and non-CVS Health owned network pharmacies to substitute the less costly generic drugs as mandated by State generic substitution laws; (c) would have “submitted [PDE] data [that] is accurate, complete and truthful”; and (d) made truthful attestations about its compliance with the law.

277. The harm alleged goes directly to the quality of healthcare the SilverScript beneficiaries have received. CVS Health itself recognizes that, “when prescriptions are more affordable, patients are more likely to keep taking them – and that leads to healthier people and communities.”¹⁷⁶ Despite this recognition, and in violation of the promised firewalls between these

¹⁷⁶ Exhibit 2 (CVS-001427).

entities, CVS Health and its wholly owned subsidiaries conspired to carry out the SSG/DNS Scheme and thus recklessly disregarded the adverse health impact it has had on Medicare Part D beneficiaries.

VII. CVS HEALTH FRAUDULENT SINGLE SOURCE GENERIC SCHEME

278. The SSG/DNS Scheme was initially offered for SilverScript and other Medicare PDP Sponsors which contracted with CVS Caremark for PBM Services.¹⁷⁷ Beginning in 2019, however, out of concerns that other PDP Sponsors (which had far fewer LIS beneficiaries) would have far more members push back on the illegality of the conduct, CVS Health made the intentional decision to restrict the SSG/DNS Scheme only to its SilverScript standalone PDP where (because it had a high percentage of LIS members whose copayments would see little impact) it would encounter very few complaints.

279. Until 2018, even though it had engaged in systematic misinformation and deception in its coverage determination process, CVS Health still routinely had approved all SilverScript SSG formulary exceptions, thus still allowing beneficiaries access to less costly generic drugs, even in situations where the beneficiary would be receiving the clinically equivalent authorized generic.

280. Only in late 2018 with the CVS Caremark's addition of Gilead's Harvoni and Epclusa to the SSG/DNS Scheme (as alleged below) did SilverScript begin its blanket denials of formulary exceptions for the SSG/DNS Drugs. Likewise, in violation of its obligation that it "must offer the Part D benefit uniformly,"¹⁷⁸ the CVS Caremark deals required that the CVS Pharmacies no longer stock the authorized generics of: (a) Gilead's Harvoni and Epclusa, and (b) GSK's

¹⁷⁷ Exhibit 3 (CVS-002069).

¹⁷⁸ CMS, Reinterpretation of the Uniformity Requirement (April 27, 2018).

Advair Diskus and Ventolin HFA. Most alarming is that this has meant not only that the authorized generics were unavailable to SilverScript beneficiaries who fill scripts at the CVS Pharmacies, but also would not have been available to the 45 million Part D beneficiaries, many of whom would have filled their prescriptions at a CVS Pharmacy. In 2019, some 34.55% of all prescriptions filled in the U.S. were filled at a CVS Pharmacy.

A. The SilverScript PDP

281. In total, SilverScript is one of the largest standalone Medicare Part D Program plans, having 5.994 million beneficiaries in 2019¹⁷⁹ and 6.134 million beneficiaries in 2018.¹⁸⁰ For 2019, SilverScript offered three plans: SilverScript Choice, SilverScript Plus, and SilverScript Allure.

282. For the SilverScript plans, the drugs included on its formularies are categorized into five cost-sharing tiers. The formulary tiers indicate the level of cost-sharing for a covered drug. In general, the higher the tier (*e.g.*, Tier 5), the higher the beneficiary's out-of-pocket cost for the covered drug. The 5 tiers are: Cost-Sharing Tier 1: Preferred Generic; Cost-Sharing Tier 2: Generic; Cost-Sharing Tier 3: Preferred Brand; Cost-Sharing Tier 4: Non-Preferred Drug; Cost-Sharing Tier 5: Specialty Tier.

283. The majority of the SilverScript beneficiaries are in the SilverScript Choice Plan, while approximately 180,000 beneficiaries are in the SilverScript Plus Plan, and approximately 10,000 beneficiaries are in the Allure plan. About 40-50% of the Choice Plan are LIS beneficiaries receiving Extra Help from Medicare resulting in subsidized costs for prescriptions; very few beneficiaries in the Plus and Allure plans are subsidized. SilverScript has more LIS beneficiaries

¹⁷⁹ CVS Health 2020 Annual Report, at 80.

¹⁸⁰ CVS Health 2019 Annual Report, at 71.

than any other Medicare Part D plan in the U.S.

284. For those SilverScript LIS beneficiaries who receive Extra Help, all or some of the copayments and cost-sharing usually paid by beneficiaries is instead subsidized by Medicare.

285. This fact made SilverScript particularly susceptible to abuse through the SSG/DNS Scheme. Because the LIS beneficiaries did not see large differences in their out-of-pocket expenses, CVS Health senior leadership overseeing the SSG/DNS Scheme concluded these beneficiaries were less likely to be price sensitive and therefore would be less concerned with the large copayment differences between the brand-name drugs and their generic versions.

286. The costs for subsidizing low-income beneficiaries are significant. The Federal Government pays approximately 18% of the drug cost of Medicare Part D for non-low income beneficiaries. The Federal Government subsidizes on average 65% of the drug cost of Medicare Part D for each beneficiary receiving the low income subsidy benefit.¹⁸¹

287. Even though the Executive Committee members understood there would be significant impact on non-LIS beneficiaries whose Catastrophic Coverage Stage was not subsidized by Medicare, they concluded that the few complaints they would receive from non-LIS beneficiaries would not be enough to offset the significant profits that CVS Caremark would garner from the illegal scheme.

B. CVS Health's False Public Statements Concerning Its Preference for Less Costly Generic Drugs and that Its SSG/DNS Scheme Would Not Increase Beneficiary Costs

288. The SSG/DNS Scheme also required CVS Health to make what it knew were

¹⁸¹ 2012 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, April 23, 2012, p. 167, available at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-andReports/ReportsTrustFunds/Downloads/TR2012.pdf.

outright false public statements to conceal its illegal scheme. For example, CVS Health Vice President for Government and Public Affairs Melissa Schulman on March 5, 2019 publicly professed that CVS Health aimed to get the “right drug at the lowest possible cost for patients. . . .” and allow patients to “stay on the medications they need”:

At CVS Health, we believe the high price of prescription drugs is among the most pressing health care issues facing Americans today. We are committed to finding the **right drug at the lowest possible cost for patients** to ensure they are able to access and **stay on the medications they need**.

289. Schulman also claimed that its PBM, CVS Caremark, was “focused” on “help[ing] lower costs for clients and their plan members” and “negotiating for greater discounts from manufacturers on their behalf”:

As a PBM, CVS Caremark is focused on developing strategies that **help lower costs for clients and their plan members**, and negotiating for greater discounts from manufacturers on their behalf. In 2017 despite a nearly 10 percent increase by manufacturers on brand list prices, CVS Caremark kept drug price growth nearly flat (0.2 percent) and lowered member monthly out-of-pocket costs, which helped improved adherence.

CVS Health is proud of our proven record of using innovative tools to hold down net costs. However, more can, and must, be done to provide prescription drug price relief and we support the Trump administration’s focus on this important issue.¹⁸²

290. Even more troublesome, Schulman touted that CVS Health was in favor of eliminating pharmaceutical manufacturer efforts to block competition: “We actively support policies that would eliminate practices by drug manufacturers to block competition, which limit our ability to secure more affordable medications for consumers and clients.”¹⁸³

¹⁸² March 5, 2019 Statement of CVS Vice President for Government and Public Affairs, “*HHS Rebate Rule 101: What Payors Need to Know*,” available at <https://payorsolutions.cvshealth.com/insights/hhs-rebate-rule-101>.

¹⁸³ *Id.*

291. In reality, the CVS Health SSG/DNS Scheme became the centerpiece in enabling the Drug Makers' anticompetitive strategies to block competition, including through deals which facilitated product hopping, patent evergreening, sham patent infringement suits, sham Citizen's Petitions, authorized generics and other schemes. The SSG/DNS Scheme of blocking generics became a key tool to impede generic competition in the marketplace, and was aimed at harming elderly, ESRD and disabled Medicare Part D beneficiaries.

292. In a piece by Derica Rice (Executive Vice President, CVS Health, and President, CVS Caremark) posted on the CVS Health website on March 19, 2019, discussing PBM pricing models, he mentions various examples of "Changing Market Trends" in drug pricing. According to Rice, "[a]fter years of double-digit list price inflations, as public outcry grew, manufacturers began to adopt new strategies either to maintain market share, or simply avoid having to drop drug list prices outright to a sustainable level."¹⁸⁴

293. One of the examples Rice provides is that the makers of Harvoni had introduced an authorized generic of the drug in 2018. He then says that CVS Caremark has "been able to use our **proven cost management strategies and negotiated with manufacturers to help ensure plan members had access to appropriate therapies while clients could focus on controlling plan costs.**"¹⁸⁵

294. This was a lie. What Rice fails to mention is that the "proven cost management strategies" CVS Caremark used for Harvoni provided neither "access" to the less costly generic

¹⁸⁴ Derica Rice, *Why the Time is Right for a New Pricing Model: As Market Trends Evolve, Payors Need an Adaptable Approach* (March 19, 2019), available at <https://payorsolutions.cvshealth.com/insights/why-the-time-is-right-for-a-new-pricing-model>.

¹⁸⁵ *Id.* (emphasis added).

version of Harvoni, nor did it control plan costs. Instead, behind the scenes CVS Caremark had entered into a secret rebate agreement with Gilead to take advantage of its position to reap huge profits for itself by blocking the less costly authorized generics and making the more expensive brand-name Harvoni and Epclusa the only options.

295. Three weeks later, on April 9, 2019 in testimony before the United States Senate Committee on Finance, Rice told members of the Senate that CVS Caremark’s goal was simple: “to reduce costs and improve health outcomes. We do this by negotiating discounts with manufacturers, designing formularies that encourage the use of generics and biosimilars, and creating new tools to help bring escalating drug prices under control.”¹⁸⁶

296. Likewise, in a bit of sleight of hand, Rice told the Committee in his written comments how important access to generic drugs was to ensuring patient adherence and healthy outcomes, saving lives: “[W]e encourage the use of generics . . . because they are proven to improve adherence and outcomes, while also lowering costs. Our research shows that **use of generics actually improves outcomes and saves lives, largely because they are more affordable for patients and therefore increase patient adherence to their medicines.**”¹⁸⁷

297. There were those on the Committee who challenged what Rice was saying. During the hearing, Senator Wyden asked Rice why CVS Caremark was putting “artificial barriers between patients and less costly medicines” by not allowing access to identical authorized

¹⁸⁶ *Drug Pricing in America: A Prescription for Change, Part III: Hearing Before the S. Comm. on Finance*, 116th Congress (2019) (Written Testimony of Derica Rice), available at: <https://www.finance.senate.gov/imo/media/doc/CVS%20Health%20SFC%2004%2009%2019%20Final.pdf>.

¹⁸⁷ Derica Rice written comments to the Senate Finance Committee at 2 (emphasis added).

generics, and asked whether it is “because you get a bigger rebate on a more expensive drug?”¹⁸⁸:

[Senator Wyden] [You as a pharmacy benefit manager] consistently say— this is your message: you bring value and fight for the lowest price. So I am going to use a couple of examples to try to see how that works in the real world. . . . [One drug maker] recently launched an identical version of [its brand-name] drug that cost 60 percent less than the original. Now here is a copy of a prior authorization form that CVS requires doctors to fill out if the doctor wants to prescribe a less costly version of this cholesterol drug. I am going to ask unanimous consent to enter this document into the record.

. . . The CVS forms says, and I quote: “The two products are the exact same, and they are made in the same manufacturing facility.” But they ask the doctor to answer detailed questions about the patient’s medical history. **Mr. Rice, why is CVS—based on this form—putting arbitrary barriers between patients and less costly medicine? Is it because you get a bigger rebate on a more expensive drug?**

298. In response, Rice dodged the question, instead testifying that what CVS “tend[s] to do” is to look at the net savings to members “to keep out-of-pocket costs low, . . . And in that particular scenario, the branded drug was still the lowest cost”¹⁸⁹:

Mr. RICE. Senator, I understand your question, and the short answer is, **absolutely not**. What you may find is that, in many cases, the highest list price drug, or the lowest list price drug in the particular example you cite, may not be the absolute lowest-cost drug. So what we tend to do is, we look at the drug’s cost after all discounts have been taken into account, because that then is what allows members to keep out-of-pocket costs low as well as the plans to keep their premiums low for their members. **And in that particular scenario, the branded drug was still the lowest cost** for——

Not true. It does not keep member out-of-pocket costs low at all.

299. According to CVS, members “win” on net price.¹⁹⁰

Senator WYDEN. You are making the argument the consumer somehow, **by your analysis, wins on net price. Is that the argument you are making?**

¹⁸⁸ *Id.* at 15 (emphasis added).

¹⁸⁹ *Id.* (emphasis added).

¹⁹⁰ *Id.* (emphasis added).

Mr. RICE. Yes, Senator.

300. And, in response to similar questioning from Senator Menendez, who asked about how long it would take CVS to add an authorized generic to its formulary, and challenging the excuse of the authorized generic having “different national [drug] codes,” Rice again dissembled, insisting again CVS would “absolutely” put the authorized generic as a “preferred drug” on its formulary when it resulted in the “lowest net cost for the patient as well as for the plan”¹⁹¹:

Senator MENENDEZ. Finally, when a drug company does lower their list price, how long does it take for the patient at the pharmacy counter to see that savings, if ever? Let me give you an example. Last fall, you may have read in the news that the list price for one . . . drug, went down by 60 percent. Despite the price decrease, putting the drug’s price below the threshold for specialty tier status, I recently read that PBMs have kept the drug on a specialty tier, which means it is more expensive for Medicare beneficiaries. [C]an you tell me in one or two sentences why a list price cut would not lead to lower prices for consumers? And if you are going to tell me it is the different national codes, then if you get guidance on how to handle this NDC issue, can we expect lower list prices leading to immediate tier changes? . . .

Mr. RICE. Senator, when those lower list prices result in the lowest net cost for the patient as well as for the plan, then absolutely, that is the preferred drug on formulary.

301. As alleged herein, Rice’s “lowest net cost” explanation was simply false. There are numerous examples set out herein where CVS Caremark’s clandestine deals with the Drug Makers to block less costly generics (many of them identical authorized generics) resulted in higher costs to the SilverScript beneficiary and to Medicare.

302. Likewise, even though Rice touted CVS Caremark’s efforts to improve patient adherence to their medications by increasing utilization of generic drugs, in fact as alleged herein, there are tens of thousands of instances in which its SSG/DNS Scheme did exactly the opposite.

¹⁹¹ *Id.* (emphasis added).

Rather than “simplifying prescription management for patients” and increasing adherence to generic medications so that patients would be able to afford their medications, the SSG/DNS Scheme in many instances has resulted in patients ceasing altogether their drug treatment due to the significant increases they faced in the cost of these drugs in addition to the barriers to access the needed drugs.

303. When confronted directly with questions about the SSG/DNS Scheme, CVS Caremark has simply lied. According to a story jointly written by ProPublica and the New York Times, the authors disclose that in December 2016 CVS Caremark had “sent a memo to pharmacies informing them that some of its Medicare prescription drug plans would cover only brand-name versions of 12 drugs. Some of the drugs, such as the antipsychotic medication Invega, have had generic competitors for over a year.”¹⁹² Access to needed medications is a primary and critical concern of CMS’s for Medicare beneficiaries.

304. The authors then tell the story of Lisa Hopkins, a 50-year-old disabled food and nutrition supervisor from Eagleville, Pennsylvania (located in this District), who had attempted to fill a prescription for Voltaren Gel, and was told by her pharmacist that her drug plan, SilverScript, denied her claim because it was for a generic.¹⁹³ “I said to the lady at the insurance company, ‘That’s really, really odd to me,’” Hopkins said. “She said, ‘Yes. It’s happening more and more

¹⁹² Charles Ornstein, Katie Thomas, *Take the Generic Drug, Patients Are Told — Unless Insurers Say No*, ProPublica (Aug. 6, 2017), <https://www.propublica.org/article/take-the-generic-drug-patients-are-told-unless-insurers-say-no>; see also Charles Ornstein, Katie Thomas, *Take the Generic, Patients Are Told. Until They Are Not*, New York Times (Aug. 6, 2016), <https://www.nytimes.com/2017/08/06/health/prescription-drugs-brand-name-generic.html>.

¹⁹³ *Id.*

that the name brand is covered but the generic isn't.”¹⁹⁴ Hopkins has osteoporosis and bulging spinal disks and has been on disability for almost a decade. She is covered through Medicare and receives extra help subsidy from the government for her medications, lowering her out-of-pocket costs. That means that when her drugs cost a lot, taxpayers pay the bill.¹⁹⁵ Even for subsidized beneficiaries, the cost share differential between a generic/multisource drug and a brand name drug can be substantial for them, usually in the range of \$5-6 per prescription.

305. When questioned by the ProPublica/Times reporters, a spokeswoman for CVS Caremark, Christine Cramer (Senior Director, Public Relations), responded that consumers would never pay more in the rare instances in which the company favors a brand-name drug over a generic: “**This generally occurs when there is limited or no competition among generics,**” she said.¹⁹⁶ This was an outright lie. Not only was the brand-name Voltaren Gel already more expensive than the less costly authorized generic, because the pharmacy was in Pennsylvania, a mandatory generic substitution State, CVS Health deprived Hopkins’ right under State law to have the less costly generic prescription substituted.

306. While CVS Health hypes in public statements the cost savings that generics offer, in actuality its SSG/DNS Scheme operates exactly counter to this. Instead of providing savings for members and Medicare, CVS Health has coordinated efforts of its vertically integrated subsidiaries to line its pocket with huge profits from the SSG/DNS Drugs.

C. CVS Health Has Touted the SSG Strategy to Its Customers While It Conceals Its Deception of Medicare Part D Beneficiaries

307. At least initially in 2014 when the SSG Strategy started, it worked legitimately as

¹⁹⁴ *Id.*

¹⁹⁵ *Id.*

¹⁹⁶ *Id.* (emphasis added).

a program aimed at saving the PDPs and beneficiaries money by taking advantage of the fact that, when first released, the first ANDA and therefore single source generic drugs may not offer significantly lower pricing than the brand-name option due to the 180-day first applicant ANDA generic marketing exclusivity. So, with only a single generic competitor, the brand-name option could be an economically more viable option, particularly when coupled with manufacturer rebates. Only when multiple generic options are introduced does the competition between multiple options often lower prices significantly. This is consistent with the FTC's analysis of so-called "House Brand Strategies,"¹⁹⁷ and the FDA's analysis of the impact of generic competition.¹⁹⁸

308. When the SSG Strategy began, as part of making it more palatable to its customers, CVS Health had ensured that it would be cost neutral to beneficiaries and Medicare, meaning that it made sure preferring the higher-cost SSG/DNS Drugs would not increase costs to beneficiaries or to Medicare.

309. However, by 2015, CVS Health management had decided not to share all of the savings generated through the SSG Strategy, and instead they would conceal the fact that many of the SSG/DNS Drugs would no longer be cost neutral for SilverScript beneficiaries. Thus began the illegitimate SSG/DNS Scheme alleged herein.

310. The SSG Strategy, as initially envisioned in 2014, sought to exploit the economics to prefer brand-name options only when a single generic alternative existed. In numerous customer presentations throughout the United States, including to PDPs contracting with CVS Caremark,

¹⁹⁷ Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies, Federal Trade Commission, at 78-80 (Aug. 2005).

¹⁹⁸ Report: *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, U.S. Food & Drug Administration (Dec. 2019), at 2-3.

CVS Health touted that Single Source Generics were not always more cost effective than the brand-name drug:

Single-Source Generics Aren't Always the Most Cost-Effective Choice

<ul style="list-style-type: none"> • In most cases, generics cost less than branded prescription drugs • Members and clients generally save when plan designs encourage generic use • However, single source generics challenge this model 	<p>SINGLE-SOURCE GENERICS: A NEW CHALLENGE</p> <ul style="list-style-type: none"> • SSGs are new-to-market generics produced by a single manufacturer • Historically, pricing for SSGs has been approximately the same or higher than branded drugs because of exclusivity
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The launch of a single source generics presents challenges for both clients and members

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311. CVS Health told PDPs contracting with CVS Caremark throughout the United States, *that they could “maximize” savings using brand-name drugs*²⁰⁰:

¹⁹⁹ Exhibit 4 (CVS-002524).

²⁰⁰ *Id.*

Single-Source Generic Strategy Can Help Minimize Disruption, Maximize Savings

BENEFITS	PRESCRIPTION SAVINGS
<ul style="list-style-type: none"> • Helps minimize the negative impact of high-cost SSG launches <ul style="list-style-type: none"> – Mitigate member disruption (i.e., limited supply or possible cost differential) – Protect rebates in the budgeting process – Maximize prescription savings 	<ul style="list-style-type: none"> • Based on review of your membership, participation in the SSG strategy would yield a per script savings of \$42.30 to \$123.25.

1. Client results will vary based on plan design, formulary status, and demographic characteristics, among other factors not listed.
 2. Non-LCS members. Source: CVS Caremark Analytics, 2019.
 Projections based on CVS Caremark data. Individual results will vary based on plan design, formulary status, demographic characteristics and other factors.
 Client-specific modeling available upon request. CVS Health uses and shares data as allowed by applicable law, our agreements and our information firewall.

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312. Likewise, CVS Health pitched to PDPs contracting with CVS Caremark throughout the United States that it had a “dedicated team” which engaged in “continuous surveillance and analysis of market events and pricing” to determine when to enter into a Single Source Generic agreement with a brand-name drug manufacturer. It reassured customers concerning the legality of the SSG program because CVS Health had the “operational infrastructure” in place to “ensure that all systems and processes align, including *applicable regulations*”²⁰¹:

²⁰¹ *Id.* (emphasis added).

Targeted Approach Ensures Success for Participating Clients

IMPLEMENTATION AND MANAGEMENT OF THE SSG STRATEGY

- Continuous surveillance and analysis of market events and pricing to determine when to cover the SSG
- Dedicated team to coordinate the implementation and management of SSG opportunities and launches
- Operational infrastructure to ensure all systems and processes align, including applicable regulations
- Criteria specifically designed to deliver improved return on investment for participating clients

Eligible clients can opt in or opt out on an annual basis.

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313. According to the sales pitch, by keeping the brand-name drug as the only formulary option and excluding the generic options, PDPs contracting with CVS Caremark would have available the brand-name drug at similar pricing as the generic. As one CVS Health presentation put it: “Members and clients generally save when plan designs encourage generic use. However, single source generics challenge this model.”²⁰²

314. CVS Health even went so far as to claim that the SSG Strategy would benefit beneficiaries financially: “Once a generic is available, CVS will apply one of two strategies, *based on financial benefits to members*: Do not include the SSG on the formulary; maintain the brand-name drug in the existing tier OR Do not include the SSG on the formulary; down tier the brand-name and reduce the member copay. Note: the typical period of exclusivity for the first generic

²⁰² Exhibit 5 (CVS-002536).

manufacturer is 180 days.”²⁰³

315. What CVS Health did not tell its PDP customers contracting with CVS Caremark was that, under the illegal SSG/DNS Scheme it initiated in June 2015, there would be no financial benefit to members. Instead, the SSG/DNS Drugs would in fact often be much more expensive than the generic versions which were being blocked. The result was that for the SSG/DNS Drugs CVS Health was choosing the more (often much more) expensive brand-name drug.

316. Even though PDPs contracting with CVS Caremark were unaware that, for some of the SSG/DNS Drugs, the brand-name drug would be more expensive than the generic to the Part D beneficiary, CVS Health’s wholly owned standalone Part D plan SilverScript was very much aware of the price impact the Scheme would have on its Part D beneficiaries.

317. Confidential Informant No. 1 (“CI-1”), a former CVS Medicare Part D actuary for SilverScript from 2017 until 2019, explained that beneficiaries and Medicare were often the losers, pointing in particular to the SSG drug Copaxone, a drug that cost \$85,000 a year. CI-1 acknowledged that “there are winners and losers,” admitting that SilverScript marketing claims that its “always” looks out for its beneficiaries were often inaccurate: “Marketing folks don’t understand the details — there should be asterisks everywhere — maybe 70% of the time what they say is true, but they can’t asterisk everything. Marketers don’t get into the nitty-gritty.”

318. Initially, when the SSG Strategy began in 2014 up through 2018, SilverScript beneficiaries who requested formulary exceptions through the coverage determination process were universally approved. Even while it tried to keep beneficiaries in the dark about the other, less costly options, SilverScript did not block the beneficiaries from getting the non-formulary

²⁰³ Exhibit 3 (CVS-002069) (emphasis added).

options as long as they were specifically requested and supported by the requisite information.

319. This all changed when CVS Caremark entered into the agreements in late 2018 with Gilead for Harvoni and Epclusa whereby it agreed it would require SilverScript to deny all coverage determinations and appeals. Not only had CVS Caremark agreed SilverScript would universally block all coverage determinations and appeals for the Gilead drugs, its agreements required as well that the CVS Pharmacies would not stock the Gilead drugs as well as the GSK drugs Advair Diskus and Ventolin HFA on their shelves.

320. Publicly, CVS Health has championed the SSG Strategy as beneficial both to beneficiaries and Medicare. For example, CVS Health has told its customers that a drug will be “eligible for consideration in the SSG Strategy if including the drug will, on average and in the aggregate, result in *equal or lower cost to the plan and members*, versus use of the newly introduced SSG.” (emphasis added).²⁰⁴ Elsewhere, CVS Health has similarly touted potential savings in a presentation example: “Based on review of your membership, participation in the SSG strategy would yield a per prescription savings of \$42.30 to \$123.25.”²⁰⁵

321. Although the SSG Strategy was initially set up in 2014 to save monies for Medicare and for beneficiaries, since the inception of the illegal SSG/DNS Scheme in June 2015, for certain SSG/DNS drugs the only winner has been CVS Health. Medicare and the SilverScript beneficiaries have been the losers. The SSG/DNS Scheme was turned into a fraudulent scheme designed to block competition by keeping prices artificially high for certain SSG/DNS Drugs while CVS Health passed on the increased cost to elderly, ESRD and disabled SilverScript beneficiaries and to U.S. taxpayers.

²⁰⁴ Exhibit 6 (CVS-002488).

²⁰⁵ Exhibit 7 (CVS-002513).

D. The Drugs Included in the SSG/DNS Scheme

322. Out of the some forty drugs that have been active in the SSG program up through 2019, the following brand-name drugs in the illicit SSG/DNS Scheme have caused significant increased costs to both Medicare and SilverScript beneficiaries alike:

1. Copaxone (Teva)
2. Exelon (Novartis)
3. Voltaren Gel (Endo)
4. Invega (Janssen)
5. Asacol HD (Allergan)
6. Xopenex HFA (Sunovion)
7. Renvela Packets (Sanofi)
8. Renvela Tablets (Sanofi)
9. Istalol (Bausch & Lomb)
10. Harvoni (Gilead)
11. Epclusa (Gilead)
12. Ventolin HFA (GSK)
13. Canasa Rectal Suppository (Allergan)
14. Advair Diskus (GSK)
15. Suboxone Sublingual Film (Indivior)

323. These drugs account for significant claims dollars. In 2018 alone, SilverScript had 3,800,171 claims for these drugs, with total costs to SilverScript of some \$1,574,283,814.75:

Generic Name	Brand Name	Number of Claims	Total Cost
Glatiramer-Sofote	Copaxone Syn 40Mg/ML-ML*	25638	\$147,414,508.39

Glatiramer-Sofote	Copaxone Syn 20Mg/ML-ML*	7803	\$53,870,483.11
Rivastigmine	Exelon 4.6 MG/24	34338	\$23,957,768.11
Rivastigmine	Exelon 9.5 MG/24	47227	\$32,644,966.40
Rivastigmine	Exelon 13.3 MG/24	20671	\$14,759,200.84
Diclofenac Sodium (Topical)	Voltaren Gel 1%	764512	\$72,390,304.15
Paliperidone-Sofoidone	Invega Tab 9Mg-9MG*	22935	\$36,652,397.03
Paliperidone-Sofoidone	Invega Tab 3Mg-3MG*	22259	\$23,855,848.81
Paliperidone-Sofoidone	Invega Tab 1.5Mg-5MG*	4122	\$4,094,059.39
Paliperidone-Sofoidone	Invega Tab 6Mg-6MG*	37831	\$50,290,584.36
Mesalamine-Sofoamine	Asacol HD Tab 800Mg-800MG*	18314	\$21,079,720.09
Levalbuterol Artrate	Xopenex INH HFA 200	85862	\$7,556,471.22
Sevelamer-Sofate	Renvela Pow 2.4Gm-4GM*	6087	\$12,404,198.73
Sevelamer-Sofate	Renvela Pow 0.8Gm-8GM*	4028	\$7,062,090.35
Sevelamer-Sofate	Renvela Tab 800Mg-800MG*	188590	\$286,846,157.87
Timolol-Sofo(ophth)	Istalol Sol 0.5% Op-OP*	7140	\$2,421,727.25
Ledipasvir-Sofobuvir	Harvoni Tab 90-400MG*	5799	\$186,167,824.22
Sofosbuvir-Sofotasvir	Epclusa Tab 400-100*	4815	\$121,064,301.23
Albuterol Sulfate	Ventolin INH HFA 200	1734708	\$109,387,787.39
Albuterol Sulfate	Ventolin INH HFA 60	5947	\$152,366.24
Mesalamine-Sofoamine	Canasa Sup 1000Mg-1000MG	5390	\$6,294,657.70
Fluticasone-salmeterol	Advair Diskus INH 250/50	385562	\$189,769,808.04
Fluticasone-salmeterol	Advair Diskus INH 500/50	130831	\$85,347,888.82
Fluticasone-salmeterol	Advair Diskus INH 100/50	78870	\$31,647,453.54
Buprenorphine HCL-Sofol-naloxone HCL dehydrate	Suboxone Mis 12-3MG	8	\$2,654.28
Buprenorphine HCL-Sofol-naloxone HCL dehydrate	Suboxone Film Sl 8-2MG	135416	\$43,611,284.47
Buprenorphine HCL-Sofol-naloxone HCL dehydrate	Suboxone Film Sl 2-0.5	8086	\$1,339,153.90
Buprenorphine HCL-Sofol-naloxone HCL dehydrate	Suboxone Film Sl 4-1MG	7382	\$2,198,148.82
TOTALS:		3,800,171	\$1,574,283,814.75

E. The CVS Defendants Have Submitted Invalid PDE Records or Statements in Support of Claims for Unsubstituted Brand-Name Drugs in Violation of State Mandatory Generic Substitution Laws

324. The claim records for the SSG/DNS Drugs show two things clearly. First, CVS is forcing CVS Pharmacies and non-CVS pharmacies alike to dispense brand-name drugs illegally

in States with laws requiring mandatory generic substitution.²⁰⁶ Thus, without the required generic substitution, the prescription was not a valid prescription under State pharmacy law and cannot be reimbursed by Medicare. Second, even in states without mandatory generic substitution laws, the SilverScript claims records show that the DAW codes submitted on claims for the SSG/DNS Drugs were inaccurate when dispensing the brand-name drug instead of the generic. Causing claims to be submitted with inaccurate DAW codes constitutes the submission (or causing the submission) of false claims.

325. Even though its contract with CMS required it to follow State mandatory generic substitution laws, SilverScript has failed to require the CVS Pharmacies and non- CVS owned network pharmacies to substitute generic drugs for much costlier brand-name SSG/DNS Drugs, and has submitted to CMS untruthful, inaccurate and incomplete PDE records and statements in support of those false claims for payment of the SSG/DNS Drugs. Furthermore, in order to ensure that only the brand-name SSG/DNS Drugs were being dispensed, CVS Health through CVS Caremark has blocked claims from non- CVS-owned network pharmacies in States where mandatory generic substitution is required.

326. As a result, all such untruthful, inaccurate, and incomplete PDE records or statements so submitted to CMS were false and as a result violated the condition of payment that the SilverScript Plan reimburse only valid generic prescriptions (as required by State mandatory generic substitution laws), instead dispensing tens of thousands of high-cost invalid prescriptions for brand-name SSG/DNS Drugs.

327. This deception across multiple CVS Health vertically integrated business units to

²⁰⁶ Most of the time the DAW Code is “0” on those records. As such, CVS cannot explain away its failure to substitute because the pharmacy was out of stock of the generic or the prescriber indicated the brand was necessary as those conditions necessitate a different DAW Code.

implement the fraudulent scheme (and in violation of its promised firewall) can be seen in its sample answers to customers' questioning whether the SSG/DNS Scheme complies with State generic substitution laws. CVS Health recognized that many States require generic substitution and those laws could cause issues for success of the SSG/DNS Scheme. But, instead of complying with those laws, SilverScript claimed it was instead only a dispensing pharmacy issue.

328. The CVS Health document entitled "Health Plan Client Strategy and FAQs" demonstrates its canned response to questions regarding State mandatory generic substitution laws²⁰⁷:

Q5	Is this change permissible in states that mandate generic dispensing?
A5	The Medicare Part D rules allow a plan to retain a brand on the Medicare Part D formulary with a generic copay and to exclude the newly released generic. While state pharmacy substitution laws are a pharmacy issue – and not a plan issue – the generic substitution laws would not pose a barrier to this strategy because such laws generally are based on economic advantage to the member as a result of receiving the generic.
<p>Note: A few of the states with generic substitution laws have more restrictive requirements. Nonetheless, the intent of these stricter pharmacy substitution laws is that consumers of prescription drug products may realize cost savings by buying less expensive, safe drug products. This is consistent with the SSG strategy, and therefore these laws should not be problematic.</p>	

329. This response is problematic at least for the following reasons:

- First, CVS Health's statement to its customers that the mandatory generic substitution issue is a not a PDP Sponsor issue, and instead a pharmacy issue is contrary to SilverScript's obligation to follow State law and to ensure that its pharmacy network and PBM did as well.
- Second, what cannot be lost is the fact that SilverScript, CVS Caremark and the CVS Pharmacies all just happen to be wholly owned subsidiaries of CVS Health. What this obfuscation does do, though, is to ensure that the fraudulent behavior would be concealed

²⁰⁷ Exhibit 8 (CVS-001794) (emphasis added).

behind a veneer that SilverScript somehow operates at arm's length from CVS Caremark and the CVS Pharmacies. The reality remains that, and in spite of its firewall obligations, CVS Health needed the complicity of all three CVS Health subsidiaries for the SSG/DNS Scheme to succeed.

- Third, this response suggests that the intent of mandatory substitution laws to provide consumer access to less costly generic drugs is consistent with the goal of the SSG Strategy. What this does not explain is the hundreds of thousands of prescriptions where CVS Caremark network pharmacies (including numerous of its CVS Pharmacies) have filled more expensive brand-name SSG/DNS Drugs for SilverScript beneficiaries in States where mandatory substitution is required by law. There is thus no “economic advantage” to the SilverScript beneficiaries from this Scheme.

330. As explained *supra*, the CVS Caremark network pharmacies are required to dispense generic versions of brand-name drugs in seventeen mandatory generic substitution States. Such substitution is mandatory and required under both State law and Medicare laws and regulations that require the prescription to be valid under State law in order to be eligible for reimbursement.

331. Not only has SilverScript certified that the PDE records submitted to document the claims for payment of the SSG/DNS Drugs were truthful, compliant with State mandatory generic substitution laws, and compliant with Medicare's requirements to follow such State laws, it also expressly certified that the data transmitted in the PDE was “accurate and complete” to its “best knowledge, information and belief.”

332. At all times material hereto, in all instances in which SilverScript submitted PDE claims with the default DAW Code 0 when dispensing a brand-name product even when there

were available generics, such information was clearly false. As the NCPDP guidelines make clear, a DAW Code 0 “is not appropriate” for brand drugs with an available generic, and “may result in a reject” of the PDE record.²⁰⁸

333. Lest there was any doubt, in Call Letters and in regulations, CMS has made clear that authorized generics are to be considered “generic” drugs and not brand-name drugs.²⁰⁹

334. CVS Caremark’s own Administrative Manual also instructs pharmacists to “*Use the DAW 0 code when dispensing a generic drug*; that is, when no party (*i.e.*, neither Prescribing Provider, nor pharmacist, nor Participant) requests the branded version of a multi-source product.”²¹⁰ (emphasis added). CVS Caremark’s Manual thus does not allow use of DAW Code 0 for anything other than dispensing generic drugs.

335. The CVS Health entities thus submitted numerous PDE claims that show violations of State mandatory generic substitution laws and with the default DAW Code 0, in violation of the requirement to submit “accurate, complete and truthful” PDE records. For example:

- The 2019 record for a paid Copaxone claim attached hereto as Exhibit 9 indicates that the “Dispense As Written” field was submitted as “0 – NO DAW.”²¹¹ As the record makes

²⁰⁸ *U.S. ex rel. Fox Rx, Inc. v. Omnicare, Inc.*, holds that the submission of DAW Code 0 in connection with the dispensing of a brand-name product when a generic should have been substituted pursuant to state law is not factually false because DAW Code 0 simply means that there was “No Product Selection Code Indicated.” *See* 38 F.Supp.3d 398, 411 (S.D.N.Y. 2014). But the 2017 version of NCPDP updates the definition of DAW Code 0 to make that conclusion of the *Fox* court inapplicable because the new DAW Code 0 definition makes it clear that it is not to be used when dispensing brand drugs if a generic is available.

²⁰⁹ *See* CMS Call Letter (April 3, 2017); 82 Fed. Reg. 56372 (Nov. 28, 2017).

²¹⁰ Exhibit 1 (CVS-002944).

²¹¹ Exhibit 9 (CVS-001893).

clear, Copaxone (*i.e.*, the brand product), was dispensed and billed at a total plan cost allowed of \$5,878.66, with a beneficiary copayment of \$1,901.46, instead of the less costly generic despite the clear instruction that there was no Dispense as Written instruction indicated by the prescriber. Furthermore, the claim record shows that the brand Copaxone was dispensed at a pharmacy located in Florida, thus violating the obligation to dispense the less costly generic in a State requiring mandatory generic substitution (Florida).

- The 2019 record for a paid Renvela Tablets claim attached hereto as Exhibit 10 indicates that the “Dispense As Written” field was submitted as “0 – NO DAW.”²¹² As the record makes clear, Renvela Tablets (*i.e.*, the brand product), was dispensed and billed at a total plan cost allowed of \$4,290.08, with a beneficiary copayment of \$291.09, instead of the less costly generic despite the clear instruction that there was no Dispense as Written instruction indicated by the prescriber. Furthermore, the claim record shows that the brand Renvela Tablets was dispensed at the CaremarkPCS Pennsylvania Mail Pharmacy, 1 Great Valley Blvd. Wilkes-Barre, Pennsylvania, thus violating the obligation to dispense the less costly generic in a State requiring mandatory generic substitution (Pennsylvania).
- The 2019 record for a paid Suboxone Film claim attached hereto as Exhibit 11 indicates that the “Dispense As Written” field was submitted as “0 – NO DAW.”²¹³ As the record makes clear, Suboxone Film (*i.e.*, the brand product), was dispensed and billed at a total plan cost of \$240.10, with a beneficiary copayment of \$91.91, instead of the less costly generic despite the clear instruction that there was no Dispense as Written instruction

²¹² Exhibit 10 (CVS-001845).

²¹³ Exhibit 11 (CVS-002759).

indicated by the prescriber. Furthermore, the claim record shows that the brand Suboxone Film was dispensed at the CVS Pharmacy, 230 E. Ashland St, Cary Hill Plz, Brockton, Massachusetts, thus violating the obligation to dispense the less costly generic in a State requiring mandatory generic substitution (Massachusetts).

336. Moreover, in all instances in which the SilverScript submitted PDE claims with a DAW 5 code (“Substitution allowed – brand drug dispensed as a generic”), such information was materially false and misleading because it was, in fact, not dispensing the SSG/DNS Drugs as “generic drugs” at all, but as the far more expensive brand-name drugs. In order to comply with State mandatory generic substitution laws, a DAW 5 code would only have been permissible in those instances in which it was dispensing the brand-name drug at the less costly, generic price.²¹⁴ That is exactly how it described the SSG Strategy in 2014 to its customers – *i.e.*, a drug would be “eligible for consideration in the SSG Strategy if including the drug will, on average and in the aggregate, result in *equal or lower cost to the plan and members*, versus use of the newly introduced SSG.”²¹⁵ Unfortunately, on average and in aggregate is not the intent of DAW 5. DAW 5 is where a brand is priced as a generic meaning the actual cost for the beneficiary is generic

²¹⁴ *Moeckel v. Caremark, Inc.*, 622 F. Supp. 2d 663, 683 (M.D. Tenn. 2007) (“Thus, where a physician prescribes a drug and authorizes substitution, the standard across the retail and mail pharmacy industry (including Caremark’s mail order pharmacies) is to utilize the DAW 5 code where the pharmacy uses, as a function of its business operations, the brand product as its generic for that drug, and it is then reimbursed at the generic rate. As the dispensing pharmacy, it can utilize any manufacturers’ product to fill a prescription for the generic drug (one of whom might be the branded manufacturer of that drug). The DAW 5 code indicates to the payer that the pharmacy uses the branded item as its generic product.”); *Teva Pharm. Indus. Ltd. v. SmithKline Beecham Corp.*, No. CIV.A.08CV3706DMC, 2009 WL 1687457, at *2 (D.N.J. June 16, 2009) (“If a pharmacy uses the DAW 5 code, it will be reimbursed the amount usually reimbursed for the generic, even though it actually dispensed a branded product.”).

²¹⁵ Exhibit 6 (CVS-002488) (emphasis added).

pricing at the point-of-service. However, that is a far cry from using DAW 5 routinely to dispense much more expensive brand-name drugs that are, in fact, much costlier to Medicare and the member. In all instances in which SilverScript submitted PDE claims with the DAW Code 5 in States requiring mandatory substitution, such information therefore was false. It also means a drug dispensed with a DAW 5 that is not priced as a generic for the beneficiary does not meet the legitimate meaning of the DAW 5.

337. Likewise, at all times material hereto, in those instances in which the SilverScript submitted PDE claims with the DAW Code 9 (Plan requests brand), such information was false in States that require generic substitution. Even though the DAW Code 9 can be used to indicate situations in which the plan requests the brand instead of the generic, the DAW Code cannot supersede State law. Nor can the SilverScript deny a beneficiary his rights and due process under Medicare Part D to access needed Part D drugs. For example:

- The 2019 record for a paid Asacol HD claim attached hereto as Exhibit 12 indicates that the “Dispense As Written” field was submitted as “9 – PLAN REQ BRAND.”²¹⁶ As the record makes clear, Asacol HD (*i.e.*, the brand product) was dispensed and billed at a total plan cost allowed of \$190.01, with a beneficiary copayment of \$96.25, instead of the less costly generic. Furthermore, the claim record shows that the brand Asacol HD was dispensed at a pharmacy located in Maryland, thus violating the obligation to dispense the less costly generic in a State requiring mandatory generic substitution (Maryland).
- The 2019 record for a paid Istalol 5ml claim attached hereto as Exhibit 13 indicates that

²¹⁶ Exhibit 12 (CVS-001698).

the “Dispense As Written” field was submitted as “9 – PLAN REQ BRAND.”²¹⁷ As the record makes clear, Istalol (*i.e.*, the brand product) was dispensed and billed at a total plan cost allowed of \$1042.70, with a beneficiary copayment of \$129.00, instead of the less costly generic. Furthermore, the claim record shows that the brand Istalol was dispensed at a CVS Pharmacy located in Philadelphia, violating the obligation to dispense the less costly generic in a State requiring mandatory generic substitution (Pennsylvania).

338. In submitting claims records supporting the dispensing of the brand-name SSG/DNS Drugs, CVS Health has routinely utilized untruthful, inaccurate and incomplete DAW Codes, such as DAW Code 0, DAW1, DAW 2, DAW Code 5, or DAW Code 9, because it has chosen not to substitute a generic for the SSG/DNS Drugs under circumstances required to do so by Medicare Part D through incorporation of State mandatory generic substitution laws. Thus, the CVS Health entities’ certification its PDE information was “accurate, complete and truthful” was intentionally false and therefore fraudulent.

339. CVS Health through SilverScript and CVS Caremark has thus submitted (or caused to be submitted) false PDE records or statements to CMS in violation of the mandatory generic substitution laws of the States of Florida, Hawaii, Kentucky, Maine, Maryland, Massachusetts, Minnesota, Nevada, New Jersey, New York, Pennsylvania, Puerto Rico, Rhode Island, Tennessee, Vermont, West Virginia, and Wisconsin.

340. Likewise, even in states without mandatory generic substitution laws, the claims records show that the DAW codes submitted on claims for SSG/DNS Drugs were improper when dispensing the brand-name SSG Drug instead of the generic. Causing claims to be submitted with

²¹⁷ Exhibit 13 (CVS-001830).

improper DAW codes constitutes the submission (or causing the submission) of false PDE records or statements.

F. CVS Deceptively Failed to Disclose Accurate Differential Prices Available for Less Costly (Often Identical) Generic Drugs

341. CVS Health and its wholly owned subsidiaries violated the terms of its 2012 Consent Order with the FTC, the antitrust laws, and the False Claims Act by engaging in anticompetitive conduct to deceive SilverScript beneficiaries concerning accurate differential pricing of less costly generic drugs. Specifically, CVS Health conceived and directed a centrally-controlled scheme to conceal less costly differential prices in lieu of the SSG/DNS Drugs sold to SilverScript beneficiaries.

342. CVS Health was only able to implement the SSG/DNS Scheme by utilizing its control of its PDP Sponsor SilverScript, its PBM CVS Caremark and the CVS Pharmacies to ensure that it would be able to block beneficiaries from receiving accurate information about and access to less costly medications.

343. CVS Health chose to ignore its obligations under the FTC Consent Order, its obligations under its firewall, and the clear, literal instructions in CMS regulations, that it provide accurate information to elderly, ESRD and disabled beneficiaries of their choices so they might be able to choose to receive lower drug prices.

344. The deception of SilverScript beneficiaries was not only cynical (particularly because it was aimed at vulnerable elderly, ESRD and disabled patients), this was particularly the case for the SSG/DNS Drugs for which there was a less costly generic.

345. In those instances when the SSG drug had an authorized generic available as an alternative, the fraud was even more flagrant. There can be no argument that the authorized generic drug is somehow in any way inferior to the brand-name drug. The authorized generics being sold

are, in fact, *identical* to thirteen (13) of the fifteen (15) SSG brand-name drugs (Exelon, Voltaren Gel, Invega, Asacol HD, Xopenex HFA, Renvela Packets, Renvela Tablets, Istalol, Harvoni, Epclusa, Ventolin HFA, Advair Diskus, and Suboxone Sublingual Film), including the exact same active and inactive ingredients. The only difference between brand-name version and the authorized generic is superficial – *i.e.*, the label, which references the different seller and different National Drug Code (“NDC”) assigned to authorized generic. The only difference CVS Health cared about was that the brand-name drug was much more expensive, allowing it to reap huge profits (while driving up the cost for taxpayers and elderly, ESRD and disabled SilverScript beneficiaries).

346. Having a different NDC allows for significantly lower prices associated with the authorized generic. According to the February 2019 GoodRx.com pricing for these drugs, the price differences between the brand-name SSG/DNS Drugs and the identical authorized generics at CVS Pharmacies ranged between 227% (Xopenex HFA) to 4,206% (Istalol) more expensive:

Brand	Brand Cash Price	Authorized Generic Cash Price	Percentage Difference
Exelon	\$726.18	\$117.39	618%
Voltaren Gel	\$61.84	\$19.95	309%
Invega	\$1240.44	\$265.25	467%
Asacol HD	\$893.48	\$243.65	366%
Xopenex HFA	\$80.98	\$35.67	227%
Renvela Packets	\$1,686.98	\$466.85	361%
Renvela Tablets	\$540.35	\$146.45	368%
Istalol	\$391.58	\$9.31	4,206%
Harvoni	\$32,704.50	\$10,087.51	324%
Epclusa	\$25,874.46	\$6,727.50	385%
Ventolin HFA	\$67.79	\$28.99	233%
Advair Diskus	\$436.81	\$123.49	354%
Suboxone Sublingual Film	\$134.92	\$39.80	338%

347. SilverScript’s failure to disclose accurate differential prices for these authorized

generic drugs is thus particularly troubling in this instance because these less costly alternatives are in fact the *exact same drugs as the brand-name versions*.

348. Not only that, but illustrating that it had long ago forgone any honest interest in having SilverScript shift to the generic once there was more competition from other generic drug makers to drive prices lower, as of November 2020 its formularies nevertheless still retained a number of the drugs as part of the SSG/DNS Scheme despite these SSG/DNS Drugs having more than one generic competitor beyond the authorized generic:

- Copaxone (Mylan, Sandoz)
- Exelon (Sandoz, Alvogen, Amneal, Breckenridge, Mylan, Zydus)
- Voltaren Gel (Amneal, Akorn, Perrigo)
- Invega (Actavis, Amneal, Inventia, Mylan, Sun)
- Xopenex HFA (Teva, Aurobindo, Cipla, Impax, Mylan)
- Renvela Packets (Aurobindo, Dr. Reddys)
- Renvela Tablets (Amneal, Anxin, Aurobindo, Dr. Reddys, Impax, Invagen, TWI, Wilshire)
- Istalol (Akorn, Apotex, E Fougera, FDC, Hi Tech Pharmacal, Pacific, Sandoz, Valeant, Wockhardt)
- Canasa (Mylan, Sandoz, PSP, Inc., and Zydus)
- Advair Diskus (Prasco, Mylan)
- Suboxone (Alvogen, Dr. Reddys, Mylan)

349. The availability of multiple generic competitors completely undermines CVS Health's stated explanation for the SSG/DNS Scheme – *i.e.*, a single generic competitor does not bring prices lower than the brand-name drug.

350. The fact that many of the SSG/DNS Drugs remained a part of the SSG/DNS

Scheme despite the presence of multiple generic competitors demonstrates that this was merely a pretext used to enrich CVS Health (while enabling the Drug Makers' anticompetitive conduct) and not really a strategy to keep drug prices affordable for Medicare and elderly, ESRD and disabled SilverScript beneficiaries.

351. The SSG/DNS Scheme relied on systematic deception of SilverScript beneficiaries, blocking access to the less costly generic. This is exactly the point made in a 2021 JAMA Internal Medicine study which featured Medicare Part D coverage for Harvoni and Epclusa and two other drugs. According to the study, there would be substantial savings if Part D beneficiaries had access to lower priced authorized generics of these drugs. However, “[f]or patients to take advantage of these lower list prices, they must be aware that the authorized generic drug is available, be on a plan that provides coverage for the product, and find a pharmacy that has this product in stock. These requirements represent *substantial barriers to getting authorized generic drugs to patients.*”²¹⁸

352. The “substantial barriers” to a competitive market erected by the deals between CVS Caremark and the Drug Makers include:

- SilverScript’s systematic denial of beneficiary rights regarding pricing and costs of authorized generics;
- Significant additional costs for the more expensive brand-name drugs, often driving beneficiaries into the Catastrophic Coverage Stage of their Medicare Part D benefits, where these drugs were frequently unaffordable;

²¹⁸ Stacie B. Dusetzina, et al., *Patient and Payer Incentives to Use Patented Brand-Name Drugs vs Authorized Generic Drugs in Medicare Part D*, 181 JAMA Internal Medicine 1605, 1609 (Dec. 2021) (emphasis added).

- SilverScript's denial of all formulary exceptions for authorized generics forms of Harvoni and Epclusa; and
- By virtue of the CVS Pharmacies not stocking the authorized generics for Harvoni, Epclusa, Advair Diskus, and Ventolin HFA, it failed to offer uniform benefits to all Part D members.

353. CVS Health's unlawful acts in violation of the FCA, as alleged herein, arise from its (a) violation of the FTC Consent Order that it would not, directly or indirectly, make deceptive claims about the price or cost of Medicare Part D prescription drugs, and is thereby liable for civil monetary penalties of up to \$10,000 per violation, pursuant to Section 5(l) of the FTC Act²¹⁹; (b) obligation under the Federal antitrust laws not to share competitively sensitive information between its firewalled subsidiaries, which conduct was aimed at harming elderly, ESRD and disabled SilverScript beneficiaries; (c) use of materially false PDE records and statements in support of false claims; (d) submission of (or causing the submission of) hundreds of thousands of false PDE records and statements in support of SSG/DNS Drug reimbursement claims for the purpose of unlawfully obtaining fraudulent reimbursement payments higher than those authorized by law; and (e) knowingly (and systematically) deceiving SilverScript beneficiaries, blocking access to equivalent, frequently identical and less costly generic drugs, often despite being required to do so by State law.

VIII. CVS HEALTH SYSTEMATICALLY DECEIVED SILVERSCRIPT BENEFICIARIES

354. CVS Health has been explicit internally about its intentional preference for the brand-name medications in the SSG/DNS Scheme and has made clear that it takes a coordinated

²¹⁹ FTC Letter to the Honorable Irvin B. Nathan, Attorney General for the District of Columbia (May 3, 2012); *see* 15 U.S.C. § 45(l).

effort across its subsidiaries to implement the SSG strategy of maximizing rebates. As CVS Health writes: “Implementation of the Single Source Generic (SSG) Strategy includes several operational pieces to ensure exclusion of the generic product(s) and maximize the utilization of the rebated brand product.”²²⁰

355. A key part of the corrupt SSG/DNS Scheme has been the use of deceptive verbatim scripts developed by SilverScript for use in training its Customer Care Representatives (“CCRs”) how to respond to beneficiary inquiries calling in to understand why they could not get access to the less costly generic.

356. The elaborate coordination across the enterprise to execute the Scheme is illustrated by the detailed training call center representative received for how to answer beneficiary inquiries received. Confidential Informant No. 2 (“CI-2”), a former supervisor and Medicare Part D lead at CVS Health from 2014 to 2020, described CCR training as being “robust,” almost two months of full-time classroom work. During the training program, SilverScript CCRs were expected to learn everything from phone manners to CMS rules. In addition, they learned the required disclaimers established under Medicare and how to answer plan member questions using CVS’s “call flow.”

357. “It was almost like taking a college class, where we had a lecture, and we took notes, and then we’re tested on it,” CI-2 said.

358. SilverScript CCRs were expected to master use of the SSG/DNS Drug scripts in responding to beneficiaries, were regularly evaluated by their managers to ensure they were doing so, and indeed would be fired if they were not.

359. Instead of providing accurate information to encourage the use of less costly

²²⁰ Exhibit 14 (CVS-002622).

generics, SilverScript CCRs were trained to follow these directives which systematically misled beneficiaries into believing there was no less costly generic option available.

360. The SilverScript CCRs thus often became unwitting foot soldiers in the carefully coordinated deceptive activities to block access to less costly generics. Not infrequently, because the SSG/DNS Scheme ran counter to how they had been trained generally in most instances to encourage the use of less costly generics, during these calls with beneficiaries the SilverScript CCRs themselves overtly express confusion and concern with what they were being directed to do.

361. Here is a sampling of: (a) the false and deceptive SilverScript Customer Care responses SilverScript CCRs were trained to give for the SSG/DNS Drugs, and (b) instances where CCRs thereby deceived elderly, ESRD and disabled SilverScript beneficiaries, blocking access to less costly generics:

A. Copaxone

362. Glatiramer acetate is an immunomodulator medication used to treat multiple sclerosis. Teva Pharmaceutical Industries, Ltd. manufactures glatiramer acetate under the brand-name Copaxone, which was first approved by the FDA in the daily 20 mg dose in 1996 and in the three times weekly 40 mg dose in 2014.

363. Medicare Part D costs for MS drugs like Copaxone have risen dramatically in the last decade. Between 2009 and 2019, rising prices for multiple sclerosis drugs including Copaxone caused Medicare spending for these medicines to increase more than 10 times, while Part D beneficiaries saw their out-of-pocket costs increase more than sevenfold. Specifically, Part D spending on multiple sclerosis drugs jumped from on average nearly \$7,800 in 2006 to more than \$79,400 in 2016. Meanwhile, out-of-pocket average patient spending rose from \$372 to nearly \$2,700 for patients with multiple sclerosis during that same period of time. And the annual cost of

treatment for those patients climbed from about \$18,600 to almost \$75,900, or 12.8% a year.²²¹

364. In the year ending August 31, 2018, Copaxone had U.S. brand sales of \$527 million for the 20 mg/mL dose and \$2.86 billion for the 40 mg/mL dose.

365. After multiple generic manufacturers filed ANDAs challenging as invalid Teva's dosing schedule patents on the 40 mg dose of Copaxone, Teva initiated four patent infringement lawsuits beginning in 2014. On January 30, 2017, a Delaware federal judge denied Teva's infringement claims, invalidating the Teva 40mg Copaxone patents for obviousness.²²² That decision was affirmed by the Federal Circuit on October 12, 2018.²²³

366. The first generic glatiramer acetate (the 20 mg Glatopa, manufactured by Sandoz) came to market in June 2015, priced at \$5000 a month, only an \$800 a month discount to Teva's monthly price for Copaxone at the time, \$5800.²²⁴ Mylan later in October 2017 introduced 20 mg and 40 mg generics, priced the same as Glatopa. By 2018, Mylan had dropped its list price from \$5,000 a month to \$1,900 a month.²²⁵

²²¹ Ed Silverman, *Price hikes for multiple sclerosis drugs helped Medicare Part D out-of-pocket costs to skyrocket*, Stat+ (Aug. 26, 2019), available at <https://www.statnews.com/pharmalot/2019/08/26/multiple-sclerosis-prices-medicare/>.

²²² Kelcee Griffiths, *Teva Vows Appeal After 4 Copaxone Patents Invalidated*, Law360 (Jan. 31, 2017), available at <https://www.law360.com/articles/886765>.

²²³ Ryan Davis, *Fed. Circ. Rules Teva's Copaxone Patents Are Invalid*, Law360 (Oct. 12, 2018), available at <https://www.law360.com/articles/1091792/fed-circ-rules-teva-s-copaxone-patents-are-invalid>.

²²⁴ Press Release, *Sandoz announces US launch of Glatopa™, the first generic competitor to Copaxone® 20mg* (June 19, 2015), <https://www.us.sandoz.com/news/media-releases/sandoz-announces-us-launch-glatopatm-first-generic-competitor-copaxoner-20mg>.

²²⁵ Carly Helfand, *Mylan decimates the list price of its Copaxone copy. But why?*, Fierce Pharma (July 9, 2018), <https://www.fiercepharma.com/pharma/mylan-decimated-list-price-its-copaxone-copy-but-why>.

367. In response to the entry of generic competitors to Copaxone 20 mg, CVS Caremark first entered into an agreement with Teva, requiring that SilverScript add Copaxone 20 mg to the SSG/DNS Scheme on June 22, 2015. Later CVS Caremark entered into an agreement with Teva, requiring that SilverScript add Copaxone 40 mg injection to the SSG/DNS Scheme on December 1, 2017.

368. The high cost associated with Copaxone has driven beneficiaries and Medicare into the Catastrophic Coverage stage where plan costs are lower (and may be offset altogether with manufacturer rebates), but beneficiary and Medicare liability could be substantial.²²⁶

369. The Copaxone SSG/DNS Scheme was controversial at CVS Health. On multiple occasions, Confidential Informant No. 1 (“CI-1”), a former SilverScript Medicare Part D actuary from 2017 to 2019, raised concerns among CVS leadership about the high cost of the SSG Copaxone scheme on beneficiaries taking the drug. CI-1’s superiors told him that the increased Copaxone costs for Medicare and Part D beneficiaries “were not an issue” of concern because “on average 93% of [LIS] members didn’t care” since their coinsurance amounts were subsidized by the Government. According to CI-1, there was little concern from CVS Health management for non-LIS members who would be the “losers” in the SSG/DNS Scheme for Copaxone.

1. CVS Caremark Product Hopping Deal with Teva for Copaxone

370. CVS Health insists that it does not participate in product hopping schemes with drug makers. In written testimony to the Senate Finance Committee,²²⁷ CVS Health Executive

²²⁶ *The Flawed Design of Medicare Part D: A Copaxone Case Study*, 46brooklyn (August 12, 2020), <https://www.46brooklyn.com/research/2020/8/12/copaxone>

²²⁷ *Drug Pricing in America: A Prescription for Change, Part III: Hearing Before the S. Comm. on Finance*, 116th Congress (2019) (Written Testimony of Derica Rice), at 43, available at: <https://www.finance.senate.gov/imo/media/doc/CVS%20Health%20SFC%2004%2009%2019%20Final.pdf>.

Vice President and CVS Caremark President Derica Rice responded to questions about product hopping from Senator Ben Cardin, stating that CVS Health would not do a “product hopping” deal with a drug maker unless “the [new] product provides a genuine benefit to patients”:

Question [Senator Cardin]. Do you think the proposed rule anticipates a situation where a pharmaceutical company stops producing an older version of a drug when a new formulation is available, but the newer formulation is not covered by a Part D plan? Why or why not?

Answer [Mr. Rice]. Brands will sometimes cease production of an older version of a product in the interest of promoting a new formulation and preventing uptake of impending generic competition for the old formulation. This is commonly referred to as “product hopping” and allows them to keep prices artificially high. In instances that you are describing, if the newer product provides **a genuine benefit to patients we would work to get such products on formulary. Otherwise we would use traditional utilization management tools to ensure patients have access to the appropriate drugs.**

371. What Rice describes is the Copaxone scheme in which CVS Caremark not only became a willing participant, but a primary co-conspirator with Teva. His statement that CVS Health “would use traditional utilization management tools” is thus palpably false with regard to how it blocked generics of Copaxone.

372. Indeed, a House Oversight Committee report investigating drug manufacturer Teva’s Copaxone tells a quite different story than what Rice had insisted in his testimony to the Senate Finance Committee. The House Report found evidence Teva had product hopped patients from the original version of Copaxone 20 mg to a newer increased dosage version of Copaxone 40 mg, creating a 2.5 year delay in generic competition and costing the U.S. health care system between \$4.3 billion and \$6.5 billion in excess expenditures.²²⁸

373. Internal documents disclosed to the Oversight Committee reveal that Teva

²²⁸ *Drug Pricing Investigation: Majority Staff Report*, Committee on Oversight and Reform (December 2021), at 108, 109-113.

developed the new dose to extend its monopoly pricing for Copaxone by shifting patients to the new dose—which still enjoyed market exclusivity—before the existing 20 mg/mL dose began facing generic competition. Teva had invested in research to support the less frequent 40 mg/mL dose of Copaxone, despite considerable internal opposition from Teva’s own Innovative Research and Development team, which, according to one of Teva’s scientists, was “strongly against” Teva’s study into the less frequent dosing of Copaxone “since it has no scientific rationale/value.”²²⁹

374. The Oversight Committee Report details how Teva took steps to leverage PBMs like CVS Caremark into facilitating the product hop “by tying contractual rebates—the discounts provided to PBMs and payers—on Copaxone 20 mg/mL to adding Copaxone 40 mg/mL to their formularies.”²³⁰ In anticipation of competing generic versions entering the market in October 2017, the Committee found that “Teva began planning a ‘House Brand Strategy’ to contract with—and pay rebates to—PBMs and specialty pharmacies to make Copaxone 40 mg/mL the only version of the drug covered or dispensed. Teva pursued this strategy following its product hop from Copaxone 20 mg/mL to 40 mg/mL.”²³¹

375. CVS Caremark executed one such “House Brand” deal with Teva, selling access to its formularies in furtherance of the Teva product hopping scheme, blocking generic competitors from being covered on its drug formularies.²³²

²²⁹ *Id.* at 174.

²³⁰ *Id.* at 113.

²³¹ *Id.* at 121.

²³² *Id.* at xii, 108.

376. In a series of emails in January 2018, Teva’s Executive Vice President for North America, Brendan O’Grady, explained how Teva’s House Brand agreement with CVS Caremark had successfully prevented generic competition to Copaxone. In one email, a fellow employee asked Mr. O’Grady whether Teva’s position would be harmed by a health insurer decision to place Copaxone 40 mg/mL on more restrictive tiers on commercial and Medicare Part D formularies, in favor of generic alternatives. O’Grady responded that the insurer’s decision had “almost zero impact on actual prescriptions.” At the time, patients covered by the insurer accessed Copaxone through a specialty pharmacy (CVS Specialty Pharmacy) that was wholly owned by a PBM (CVS Caremark) which had entered into a House Brand contract. O’Grady explained: “Because [CVS Caremark] is getting an additional rebate to fill all ‘glatiramer’ or Copaxone scripts with Copaxone ... if a doctor orders generic glatiramer or the pharmacy benefit [manager] mandates it be filled as a generic, it will come in a plain box with Copaxone inside. Win-win for all. . . .”²³³

377. But, many SilverScript beneficiaries were left holding the bag on increased costs for Copaxone in the Catastrophic Coverage stage of their Part D benefit. Many could not afford the additional cost, and were forced to skip their treatment. The impact of blocking beneficiaries from getting access to the less costly generic glatiramer acetate instead of the costlier brand-name Copaxone has had a dramatic impact not just on the cost of the drug, but on many patients’ care. The annual cost of Copaxone by 2019 was approximately \$85,000. A recent survey by the National Multiple Sclerosis Society found that 40% of MS patients who take a DMT drug (like Copaxone) skipped or delayed filling a prescription, took less than prescribed, or stopped taking

²³³ *Id.* at 122-23.

their medication altogether due to the high cost.²³⁴ Only 11% said they could afford the medication without financial assistance.²³⁵

378. The SSG/DNS Scheme for an expensive, maintenance drug like Copaxone pushed beneficiaries into the Catastrophic Coverage stage faster, where the SilverScript financial liability is low, but where beneficiaries and Medicare are forced to pick up significant additional cost. That is because a Medicare beneficiary's progression through the Part D benefit stages is based on the prescription drug list price at the point of sale, which excludes rebates, discounts, and other fees CVS Caremark receives. This creates the perverse situation where beneficiaries reach the Catastrophic Coverage Stage (where they face potentially substantial cost sharing) sooner when using a high-priced product like Copaxone.²³⁶

2. SilverScript Deception Blocked Access to the Less Costly Generic Copaxone (glatiramer acetate)

379. SilverScript CCRs were provided training materials telling them to inform beneficiaries that making Copaxone the exclusive formulary option would help “lower out-of-pocket cost”:

<Copaxone> is a brand-name prescription drug used to treat multiple sclerosis. This prescription drug was recently launched in its generic form <(glatiramer acetate)>. Generic prescription drugs are typically the lowest-cost option when compared to brand-name prescription drugs. <Client> promotes the use of generic prescription

²³⁴ Multiple Sclerosis Society, *Quantifying the Effect of the High Cost of DMTs Market Research Report August 2019*, available at <https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Advocacy/NMS-S-Research-Report-Full-Access-to-MS-Medications.pdf>.

²³⁵ *Id.*

²³⁶ Joshua Cohen, *More Accountability Needed In Medicare Part D Plan Formulary Decision-Making*, Forbes (March 12, 2020), available at <https://www.forbes.com/sites/joshuacohen/2020/03/12/more-accountability-needed-in-medicare-part-d-plan-formulary-decision-making/?sh=378c7060779a> 1/5

drugs to help plan beneficiaries save money. During the initial launch phase for the generic, there will be few manufacturers marketing the generic and the cost of the generic is expected to be relatively high. To help lower out-of-pocket cost, <Client> is passing along a manufacturer discount on the brand <Copaxone>. As a result, <Client> will continue to keep the brand version of <Copaxone> on the formulary and will NOT be adding the generic version until further notice.²³⁷

While this may have been accurate when Copaxone was added to the SSG/DNS Scheme in 2015, the CCR statement about lowering out-of-pocket costs was no longer correct by late 2018 when other generic forms of glatiramer acetate were available at a much lower in cost to the member and Medicare Part D than the brand Copaxone. Moreover, given the fact that by late 2018 there were two competing generics (Mylan, Sandoz), there was simply no longer any reasonable explanation why brand-name Copaxone remained the only SilverScript formulary option.

380. SilverScript CCRs were also instructed that they should tell beneficiaries that they have the option to request a formulary exception, but that it would be at the “highest cost share level”:

[t]he generic equivalent, <Glatiramer acetate>, will not be on the formulary during this time. Beneficiaries will have the option to request an exception if they wish to obtain <glatiramer acetate>. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level. Brand <Copaxone> is available at the current Specialty Tier copay/coinsurance, so if the request for the generic is granted, the beneficiary would pay the amount associated with the plan’s exception tier. This may be a different cost than the brand.²³⁸

The CCR statement about exception requests was deceptive. For 2019, Copaxone was a Tier 5 drug with coinsurance of 33%. A formulary exception would have been approved for Tier 4 with a coinsurance of 40%. Thus, keeping the brand Copaxone as the only SilverScript formulary option

²³⁷ Exhibit 15 (CVS-000377-87)

²³⁸ *Id.*

would not have resulted in lower out-of-pocket costs. Moreover, the discussion about the copay for the generic of Copaxone, glatiramer acetate, was intended to discourage beneficiaries from asking for a formulary exception by using misleading terminology “highest cost share level.” This was deceptive. Even with the higher non-formulary exception tier coinsurance that would apply to the generic, if approved, due to the dramatically lower price of glatiramer acetate (generic Copaxone) will always be less expensive for Medicare and the beneficiary.

381. If SilverScript CCRs were asked by beneficiaries “[w]ill <Copaxone> cost more than <glatiramer acetate> in any stage of the Medicare D benefit,” they were told to respond: “This will vary based on what Plan you are in and which Medicare Part D coverage stage you currently are in (*e.g.*, Deductible, Initial Coverage Limit, Coverage Gap or Catastrophic).”²³⁹

382. For LIS beneficiaries inquiring about whether there would be higher costs at any stage, SilverScript CCRs were to say that “[i]n the Catastrophic stage of the benefit you will continue to receive <Copaxone> at no cost. If you have not yet reached the Catastrophic stage, you might have to pay your brand-name copayment for <Copaxone> until you reach the Catastrophic stage.”²⁴⁰ This was misleading because comparative costs are not provided to subsidy members, leaving them without information to determine actual cost differences. If SilverScript CCRs had been trained to give a truthful answer, they would have told LIS beneficiaries:

- The cost to LIS 1 beneficiaries in the initial coverage stage for CY2019 is \$8.50 for the brand and \$3.40 for the generic. The LIS beneficiary will pay \$0 for both the brand and the generic glatiramer acetate in the Catastrophic Coverage stage.

²³⁹ *Id.*

²⁴⁰ *Id.*

- Medicare Part D will pay \$2,461.55 for the brand (\$2,470.05 - \$8.50) and \$1,528.60 for the generic glatiramer acetate (\$1,532.00 - \$3.40) in the ICL stage.
- Medicare Part D will pay \$1,862.75 for the brand (\$1,871.25 - \$8.50) and \$1,413.70 for the generic glatiramer acetate (\$1,417.10 - \$3.40) for the generic in the Coverage Gap (where applicable) stage.
- Medicare Part D will pay \$374.25 for the brand and \$191.50 for the generic glatiramer acetate in the Catastrophic Coverage stage (full amount of beneficiary's cost) in addition to 80% of the cost of either drug for the Medicare portion of the cost of the drugs in this stage.

383. If beneficiaries asked SilverScript CCRs “[a]ren’t generics less expensive,” the canned response was: “When a generic version is first available, it is typically similar in price to the brand-name version. Eventually, we expect more generic prescription drug companies to start making and selling <glatiramer acetate>, which could bring down the price.”²⁴¹ The CCR statement about when generic glatiramer acetate prices will be lower than the brand was false and deceptive. Here generic glatiramer acetate was, in fact, already by 2018 were much lower in price for all beneficiaries. There was no need to wait for there to be additional generic manufacturers to bring the price down.

384. If asked, “[c]an I get the generic,” they were to tell beneficiaries:

At this time the generic version, called <glatiramer acetate>, is not on the formulary. You do have the option to request a formulary exception. However, brand <Copaxone> is available at the current Specialty Tier coinsurance/copay, so if the request for the generic is granted, you (the beneficiary) would pay the amount

²⁴¹ *Id.*

associated with the Part D plan's exception tier. This may be a different cost than the brand."²⁴²

This was deceptive. While this statement may have been true for some newly released generics, the generics for Copaxone were soon available at a lower cost option for all beneficiaries. Moreover, it was intended to discourage beneficiaries from asking for a formulary exception. A formulary exception for the generic would have been approved at the highest tier (Tier 4) with a coinsurance of 40%. However, even with the higher coinsurance, the generic glatiramer acetate was already much less expensive than the brand due to the dramatic difference in price.

385. If they were asked how long would "<COPAXONE> remain on the formulary on the <Specialty Tier (Tier 5)>," the scripted response was: "We anticipate that <COPAXONE> will remain on the formulary on the <Specialty Tier (Tier 5)> in <2018 and 2019> until the price of the generic form of <COPAXONE> drops. We anticipate it will be a <minimum of six months>, however that is based on market conditions not within our control and could change."²⁴³

386. This was misleading. As of February 2019, the GoodRx price of the generic glatiramer acetate was \$1,567.18 compared to the brand Copaxone price of \$7,170.91, already making the generic a lower cost option for both the beneficiary and Medicare.

387. Thus, the decision to keep the brand Copaxone as the only option on the SilverScript formulary was not driven by market conditions, but by CVS Health's own profit motives. This was even more deceptive by 2020, well past the promised price drop related to "market conditions."²⁴⁴ By then, there were two generics being sold competing against Copaxone

²⁴² *Id.*

²⁴³ *Id.*

²⁴⁴ *Id.*

(Mylan, Sandoz). However, even then the brand-name Copaxone remained the only choice on the SilverScript Choice and Plus formularies.²⁴⁵ Likewise, it was a lie and deceptive to say that the market conditions were not “within our control” when it was CVS Caremark’s agreement with Teva that was the cause for the delay in the formulary access to the less costly generic drug glatiramer acetate. The market conditions were thus completely within its control.

388. If beneficiaries asked whether they could request a coverage determination for the less costly generic, they were to be told: “Yes, you as the beneficiary may request a coverage determination for <glatiramer acetate>. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.” This was misleading and intended to discourage beneficiaries from asking for a formulary exception. A formulary exception for the generic glatiramer acetate would have been approved at the highest tier (Tier 4) with a coinsurance of 40%. However, even with the higher coinsurance, the generic glatiramer acetate would have been less expensive than the brand Copaxone due to the dramatic difference in price.

3. Beneficiary No. 1

389. Beneficiary No. 1’s experience showcases how, despite beneficiary protests, SilverScript did not provide beneficiaries with information or options about how to reduce their Copaxone out-of-pocket cost (and also consequently costs to Medicare) by getting access to less costly generic drugs.

390. In late January 2019, Beneficiary No. 1 (a 67-year-old woman from Nebraska) was

²⁴⁵ See 2020 SilverScript Choice Comprehensive Formulary, available at https://www.silverscript.com/pdf/FORM_2020_CHOICE_EN.pdf; 2020 SilverScript Plus Comprehensive Formulary, available at https://www.silverscript.com/pdf/FORM_2020_PLUS_EN.pdf.

able to get her prescription for the generic version of Copaxone (glatiramer acetate) under a transition fill (hereinafter “Transition Fill”), a one-time, short-term fill of a prescription as a temporary stopgap to ensure beneficiaries get their medication even if it is not otherwise supposed to be available because it is not on formulary or is not pre-approved.²⁴⁶

391. The claim record shows that the CVS Specialty Pharmacy filled her glatiramer acetate prescription and submitted the claims with a “0 – NO DAW” code.²⁴⁷

392. According to the CVS Participating Pharmacy Manual, the CVS Specialty Pharmacy could only “[u]se the DAW 0 code when dispensing a generic drug; that is, when no party (*i.e.*, neither Prescribing Provider, nor pharmacist, nor Participant) requests the branded version of a multi-source product.” (emphasis added).²⁴⁸

393. Shortly thereafter, she received a letter from SilverScript dated January 28, 2019 stating that the Transition Fill of the generic was only a one-time fill because the drug was not covered on the formulary.²⁴⁹

394. After receiving the letter from SilverScript, Beneficiary No. 1 contacted SilverScript Customer Care to figure out what she needed to do in order to keep getting the less costly medication. Over the course of two different calls, the SilverScript CCRs never gave Beneficiary No. 1 the option to request a coverage determination for the formulary exception. To the contrary, the solution SilverScript CCRs offered was for them to contact her doctor to have the doctor specify in the prescription that the brand-name Copaxone was required. So, instead of

²⁴⁶ Exhibit 16 (CVS-001933).

²⁴⁷ *Id.*

²⁴⁸ Exhibit 1 (CVS-002944).

²⁴⁹ Exhibit 17 (CVS-001934).

offering her a formulary exception, CVS Health forced the doctor to write a prescription for the brand-name Copaxone despite there being no clinical reason to use the brand-name over the generic.

395. This is non-compliant with CMS rules and regulations, and was by definition a coverage determination request for the generic Copaxone. What happened to Beneficiary No. 1 is exemplary of thousands of instances where SilverScript denied beneficiaries access to their rights under Medicare.

396. Beneficiary No. 1's claims history demonstrates how denying the option of a formulary exception made her medication more expensive to both this senior and Medicare. Given the high price of Copaxone, merely three fills pushed her into the Catastrophic Coverage Stage. In the Catastrophic Coverage Stage, the cost difference between the brand-name Copaxone and the generic are stark:²⁵⁰

	Generic (Glatiramer Acetate)	Brand (Copaxone)
Plan allowed drug cost	\$4,718.67	\$5,892.65
Member Co-pay	\$235.93	\$294.65
Plan Cost (SilverScript Cost)	\$707.80	\$883.89
Medicare Cost (Catastrophic Coverage Stage)	\$3,775.43	\$4,714.61
Total Medicare Cost	\$3,775.43	\$4,714.61

397. Illustrating the contortions to which the SSG/DNS Scheme has required SilverScript to make, here, as evidenced by Beneficiary No. 1's use of the generic version of Copaxone and continued requests for it, there was no medically valid reason her physician would have required that she needed to receive the brand-name drug instead of the less costly generic that

²⁵⁰ Exhibit 18 (CVS-001923).

had been requested. Not only had she specifically requested the generic, the generic glatiramer acetate she received was less costly and was therapeutically equivalent. Thus, a DAW 1 code in the PDE record in support of the SilverScript payment for Beneficiary No. 1 was untruthful, inaccurate and incomplete.

398. Furthermore, requiring her to use the brand-name Copaxone was invalid because the prescription was filled at a CVS pharmacy in Pennsylvania, a mandatory generic substitution State. SilverScript thus violated the State law requirement that the prescription be substituted with the less costly generic.

B. Invega

399. Paliperidone is an atypical antipsychotic used to treat schizophrenia and schizoaffective disorder. Janssen Pharmaceuticals, Inc., a wholly-owned subsidiary of Johnson & Johnson, manufactures paliperidone under the brand-name Invega. Paliperidone is a “me, too” active metabolite version of its drug risperidone (Risperdal), which had lost patent protection years earlier.

400. As of the year ending June 30, 2015, Invega Extended-Release Tablets 1.5 mg, 3 mg, 6 mg and 9 mg, had U.S. sales of approximately \$606.2 million.

401. On August 3, 2015, the FDA approved a generic version of Invega manufactured by Allergan, which announced it had launched sales of the generic tablets on September 25, 2015.²⁵¹ On September 28, 2015, Mylan announced the launch of its own generic versions of

²⁵¹ Da Hee Han, *First Generic Version of Invega Launched*, MPR (September 25, 2015), available at <https://www.empr.com/home/news/generics-news/first-generic-version-of-invega-launched/>

Invega tablets.²⁵²

402. In response to the competing Allergan and Mylan generics, on September 24, 2015, a wholly owned subsidiary of Janssen, Patriot Pharmaceuticals, LLC (located in Horsham, Pennsylvania, within this District) announced it would begin selling the authorized generic version of Janssen’s Invega (paliperidone), available as 1.5 mg, 3 mg, 6 mg, and 9 mg extended-release tablets.²⁵³

403. The authorized generic for Invega was manufactured by Janssen and was identical to the brand-name drug. The only difference was the assigned National Drug Code (NDC).

404. Patriot’s website describes authorized generics as “the innovator’s prescription drug, approved under a New Drug Application (NDA) by the FDA, and are either marketed and distributed by an authorized generic distributor or have sales and supplies managed by an entity like Patriot with a generic product label.”²⁵⁴

405. In addition, Patriot’s website says that there are no differences between the authorized generic and the brand product it is selling for Janssen: “Patients will have the same product experiences with Authorized Generics as they did with the brand-name products in areas

²⁵² *Mylan Launches Generic Invega® Tablets*, PR Newswire (Sep. 28, 2015), available at <https://www.prnewswire.com/news-releases/mylan-launches-generic-invega-tablets-300149726.html>

²⁵³ OptumRx, “Invega (paliperidone) – First-Time Generic” available at https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/vgnlive/HCP/Assets/RxNews/New%20Generics_Invega_2015-0925.pdf (last accessed June 6, 2019).

²⁵⁴ Patriot Pharmaceuticals, “About Authorized Generics” <https://www.patriotpharmaceuticals.com/patriotpharmaceuticals/faqs.html> (last accessed on June 9, 2019).

such as taste, color, mouth feel, size and shape.”²⁵⁵

406. CVS Caremark shortly thereafter entered into an agreement with Janssen, requiring that SilverScript add Invega to the SSG/DNS Scheme on November 6, 2015.

1. SilverScript Deception Blocked Access to Generic Invega (paliperidone tablets)

407. After Invega was added to the SSG/DNS Scheme, SilverScript CCRs were told to tell beneficiaries:

During the initial launch phase for the generic, there will be few manufacturers marketing the generic and the cost of the generic is expected to be relatively high. To help keep out-of-pocket costs low, SilverScript is retaining brand INVEGA TABLET on its formulary on the Preferred Brand Tier (Tier 3). INVEGA TABLET is eligible for a manufacturer discount in the coverage gap.²⁵⁶

This was misleading. Authorized generics are eligible for the Coverage Gap discount program since they are NDA “applicable” drugs.²⁵⁷ The generic drug paliperidone tablet option(s) were lower cost to the member and Medicare than the brand for the SilverScript Allure Plan in the ICL stage and for all SilverScript plans in the Coverage Gap (where applicable) and Catastrophic Coverage Stage. Moreover, given the fact that there were as of 2019 five competing generics (Actavis, Amneal, Inventia, Mylan, Sun), there was simply no longer any reasonable explanation why Invega remained the only SilverScript formulary option.

408. SilverScript CCRs were also to tell beneficiaries:

Retaining brand INVEGA TABLET on the Preferred Brand Tier (Tier 3) can help keep out-of-pocket costs low for SilverScript beneficiaries. . . . Beneficiaries will

²⁵⁵ *Id.*

²⁵⁶ Exhibit 19 (CVS-000324-33).

²⁵⁷ CMS, *Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance* (May 21, 2010), at 4.

have the option to request a formulary exception if they wish to obtain paliperidone tablet.

- However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest non-specialty cost share level (Tier 4) in 2018 and 2019.
- Brand INVEGA TABLET is available at Preferred Brand Tier (Tier 3) copay in 2018 and 2019, so if the request for the generic is granted, the beneficiary would most likely pay a higher out-of-pocket cost as the medication will pay as a Tier 4 coinsurance. As the cost of the generic is expected to be higher, the coinsurance amount will also be higher for the generic.²⁵⁸

The statement about keeping out-of-pocket costs low was misleading. Invega was at the time a Tier 3 drug. A formulary exception would have been approved for Tier 4. This would result in a higher cost for the generic paliperidone tablet in the ICL stage only (Choice, Plus) and a lower cost for the generic (Allure). For the Coverage Gap and Catastrophic Coverage Stages, the generic paliperidone tablet would be less expensive in all plans.

409. If SilverScript CCRs were asked whether “INVEGA TABLET [will] cost more than paliperidone tablet in any phase of the Medicare Part D benefit,” they were to tell non-LIS beneficiaries:

No. The Coverage Gap Stage (also called the “donut hole”) is where you will receive significant savings on brand INVEGA TABLET. The brand-name would have been less expensive than the generic version because of the manufacturer discount on brand-name prescription drugs. In 2018, your cost share in the Coverage Gap Stage is 35% on the price of brand INVEGA TABLET. If the generic were included at this time on the formulary, your cost share would be 44%. In 2019, your cost share in the Coverage Gap Stage is 25% on the price of brand INVEGA TABLET. If the generic were included at this time on the formulary, your cost share would be 37%..²⁵⁹

²⁵⁸ *Id.*

²⁵⁹ *Id.*

This was false. The reference to the higher generic cost share was misleading because, even with the higher copayment, the generic paliperidone tablet was already less costly. If they were being truthful, SilverScript CCRs would say that, in all non-subsidy scenarios across all three plans, the cost of the generic paliperidone tablet would in almost all situations always be lower.

410. If asked why beneficiaries cannot get the generic, SilverScript CCRs were trained to respond:

When a generic version is first available, it is typically similar in price to the brand version. At this time the generic version, called paliperidone tablet, is not on the formulary. You do have the option to request a formulary exception. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level (excluding the Specialty Tier - Tier 4) in 2018 and 2019. Brand INVEGA TABLET is available at the Preferred Brand Tier (Tier 3) in 2018 and 2019, so even if an exception is granted to allow coverage of the generic, you might pay more out-of-pocket for the generic version paliperidone tablet than for brand INVEGA TABLET. Eventually, we expect more generic prescription drug companies to start making and selling paliperidone tablet, and this should bring down the price.²⁶⁰

It was misleading to tell beneficiaries that the generic paliperidone tablet is not less costly than the brand-name Invega. While this statement may have been true for some newly released generics, the generic paliperidone tablet was already much lower in price for some beneficiaries in the ICL stage and all beneficiaries in the Coverage Gap (where applicable) and Catastrophic Coverage Stages. There was no need to wait for there to be multiple generic manufacturers for the price to come down since the generic was already less costly than the brand-name Invega. Likewise, it was deceptive to discourage beneficiaries from asking for a formulary exception. Only in the ICL stage of the plan would the generic paliperidone tablet be more expensive than the brand in the Choice and Plus plans, but it would always be less expensive in the Allure plan.

²⁶⁰ *Id.*

411. If asked by beneficiaries how long Invega would be the exclusive formulary choice, SilverScript CCRs were to respond: “We anticipate that INVEGA TABLET will remain on the formulary in Preferred Brand Tier (Tier 3) in 2018 and 2019 until the price of the generic form of INVEGA TABLET drops. We anticipate it will be a minimum of six months, however that is based on market conditions not within our control and could change.”²⁶¹

412. This was misleading. By February 2019, the GoodRx price of the generic paliperidone tablet was \$265.25 compared to the price of the brand Invega of \$1,240.44, making the generic already a much lower cost option for both the beneficiary and Medicare in many scenarios.

413. Thus, the decision to keep the brand Invega as the only choice on the SilverScript formulary was not driven by purported market conditions, but by CVS Health’s own profit motives. This was even more deceptive by 2020, well past the promised price drop related to “market conditions.”²⁶² By then, there were six generic paliperidone tablet products being sold competing against Invega (Actavis, Amneal, Inventia, Mylan, Patriot and Sun). However, even then the brand-name Invega remained the only option on the SilverScript Choice and Plus

²⁶¹ *Id.*

²⁶² *Id.*

formularies.²⁶³

414. Likewise, it was a lie and deceptive to say that the market conditions were not “within our control” when it was CVS Caremark’s agreement with Janssen that was the cause for the delay in the formulary access to the less costly generic drug paliperidone tablet. The market conditions were thus completely within its control.

415. If SilverScript CCRs were asked by beneficiaries whether they could request a coverage determination for the less costly generic, they were to tell them:

Yes, you as the beneficiary may request a coverage determination for paliperidone tablet. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at a higher cost share level (excluding the specialty tier). Brand INVEGA TABLET is available at the Preferred Brand Tier (Tier 3) copay in 2018 and 2019, so you might pay more out-of-pocket for the generic than for the brand at this time.²⁶⁴

This was misleading as to the Allure beneficiaries and was intended to discourage them from asking for a formulary exception. Only in the ICL stage of the plan (where this exception would be used), the generic paliperidone tablet would be more expensive than the brand in the Choice and Plus plans, but less expensive in the Allure plan.

2. Beneficiary No. 2

416. When Beneficiary No. 2 (a 34-year-old man living in Missouri) sought to fill a

²⁶³ See 2020 SilverScript Choice Comprehensive Formulary, available at https://www.silverscript.com/pdf/FORM_2020_CHOICE_EN.pdf; 2020 SilverScript Plus Comprehensive Formulary, available at https://www.silverscript.com/pdf/FORM_2020_PLUS_EN.pdf; Allure formulary, available at <https://q1medicare.com/PartD-BrowseMedicare-2019PlanFormulary.php?letter=I&formulary=00019296&contractId=S5601&planId=154&segmentId=0&zipCountyCode=0&ccountyName=Statewide&stateReg=12TN&zip=&planType=P&mcode=state&prAuth=&stepTh=&qtyLmt=&tier1=&tier2=&tier3=&tier4=&tier5=&tier6=&sort=drugNameasc>.

²⁶⁴ Exhibit 19 (CVS-000324).

prescription for the generic Invega (paliperidone tablets) on February 22, 2019, he was able to get his prescription under a Transition Fill at his pharmacy.²⁶⁵

417. Shortly thereafter, he received a letter from SilverScript dated February 26, 2019, stating that the Transition Fill of the generic was only a one-time fill because the drug was not covered on the formulary, and was required to use the brand Invega thereafter.²⁶⁶ The letter from SilverScript failed to notify Beneficiary No. 2 that there was an identical, less costly authorized generic for the brand Invega.

418. After Beneficiary No. 2 filed a grievance on March 4, 2019, SilverScript failed to address his request for a coverage determination within that grievance for the generic paliperidone, presumably because it was not covered under the plan. Despite the fact that SilverScript had for years granted all formulary exceptions whenever beneficiaries requested the less costly generic, there is no indication from the grievance notes that the representative offered him a formulary exception, which SilverScript was required to offer and which had been routinely granted up until late 2018.

419. This is non-compliant with CMS rules and regulations, and was by definition a grievance and a coverage determination request for the generic Invega. What happened to Beneficiary No. 2 is exemplary of thousands of instances where SilverScript denied beneficiaries access to their rights under Medicare.

420. While the decision to require Beneficiary No. 2 to use the brand Invega did not increase his costs since his coinsurance was subsidized (his copayment was \$3.40 for both the

²⁶⁵ Exhibit 20 (CVS-002333).

²⁶⁶ Exhibit 21 (CVS-002334).

brand and the generic), it did drive up the costs for taxpayers considerably. The paid claim record for his paliperidone ER indicates the plan allowed drug cost for the generic paliperidone was \$401.97 compared to the plan allowed cost for Invega of \$607.83, a 151% increase.²⁶⁷ These costs would only increase as Beneficiary No. 2 proceeded to the Catastrophic Coverage Stage of his benefit.

C. Asacol HD

421. Mesalamine is used to treat inflammatory bowel disease, including ulcerative colitis and Crohn's disease. Allergan manufactures mesalamine delayed-release tablets under the brand-name Asacol HD.

422. By 2014, Asacol HD's annual sales in the U.S. were \$488 million.

423. CVS Caremark entered into an agreement with Allergan, requiring that SilverScript add Asacol HD added to the SSG/DNS Scheme on September 23, 2016.

1. The Asacol HD SSG/DNS Deal Facilitated Allergan's "Pay-for-Delay" Tactics, Delaying Generic Competition

424. CVS Health has insisted that it opposes so-called "pay-for-delay" tactics from drug makers. For example, CVS Health Executive Vice President Jon Roberts posted an article on the company website on February 7, 2017, stating that the company "supports passing laws that end" pay-for-delay deals.²⁶⁸

425. In a letter to then HHS Secretary Alex Azar dated July 16, 2018, CVS Health stated that, "[b]y prohibiting pay-for-delay agreements, the Trump Administration can curb anti-

²⁶⁷ Exhibit 22 (CVS-002332).

²⁶⁸ Jon Roberts, *Bending the Prescription Drug Cost Curve: How Policy Reform Can Help*, CVS Health website (Feb. 7, 2017), available at <https://payorsolutions.cvshealth.com/insights/bending-prescription-drug-cost-curve>.

competitive practices and help bring lower cost, clinically-equivalent generic medications to market more quickly.”²⁶⁹

426. Likewise, in testimony before the Senate Finance Committee on April 9, 2019, CVS Health Executive Vice President and President of CVS Caremark Derica Rice insisted that CVS Health supports “ending ‘pay-for-delay,’ a tactic that allows brand manufacturers to pay generic competitors to keep products off the market and extend market exclusivity.”²⁷⁰

427. What CVS Health has failed to admit was that, in fact, the SSG/DNS Scheme had for years actually aided and abetted pay-for-delay Drug Maker tactics.

428. One example of this is Asacol HD. In order to protect its Asacol franchise, Allergan had engaged in numerous schemes to delay generic competition, including a product hop from Asacol to Asacol HD; a so-called “hard switch” to Asacol HD (ceasing the sale of Asacol in April 2013); a reverse payment settlement with first generic maker Zydus (effectively bottlenecking all other generics), paying it not to compete with a generic form of Asacol HD; “ever-greening” sham patent infringement litigation against generic makers to obtain a 30-month Hatch Waxman stay; and the introduction of an authorized generic version of Asacol HD.

429. In September of 2011, generic maker Zydus Pharmaceuticals had filed the first ANDA seeking FDA approval for generic Asacol HD. As the first generic filer, Zydus was potentially entitled to 180 days of restricted competition from other generics (other than

²⁶⁹ Press Release, *CVS Health Responds to Request for Information on Trump Administration's Blueprint to Lower Drug Prices*, CVS Health website (July 16, 2018), available at <https://www.cvshealth.com/news-and-insights/press-releases/cvs-health-responds-to-request-for-information-on-trump>.

²⁷⁰ See *Drug Pricing In America: A Prescription For Change, Part III*, Hearing Before the Committee on Finance, U.S. Senate, S. Hrg. 116-415 (April 9, 2019).

“authorized generics” sold by the brand company itself). In November of 2011 Warner Chilcott (later acquired by Allergan) filed a patent infringement suit in order to prevent Zydus from entering the market.

430. After two years of litigation, in late 2013 and early 2014 Warner Chilcott entered into an unlawful non-competition agreement with Zydus. In the agreement, Warner Chilcott agreed to pay Zydus tens of millions of dollars annually in exchange for Zydus’s agreement to quit its challenge to Warner Chilcott’s patent and assist in delaying the entry of a less costly generic version of Asacol HD until at least November 15, 2015, but likely by or beyond July 1, 2016. As part of the reverse payment agreement, Warner Chilcott promised (i) not to launch an authorized generic version of Asacol HD to compete against Zydus’s generic, and (ii) to deter other generic manufacturers from entering the market before Zydus.

431. According to a press release issued by Allergan in 2014, it had finalized the reverse payment settlement agreement with Zydus related to Asacol HD:

Under the terms of the agreement, Actavis will grant Zydus an exclusive license to market its generic Asacol® HD beginning on November 15, 2015, or earlier under certain circumstances, following receipt by Zydus of final approval from the U.S. Food and Drug Administration (FDA) on its Abbreviated New Drug Application (ANDA) for generic Asacol® HD. Alternatively, if Zydus does not gain FDA approval of its generic Asacol® HD by July 1, 2016, Zydus will be permitted to launch an authorized generic version of Actavis’ product beginning on July 1, 2016.²⁷¹

432. As part of the settlement, Zydus agreed to turn over 75 percent of its authorized generic profits to Actavis (which changed its name to Allergan when it bought the company in

²⁷¹ June 9, 2014 Press Release, “Actavis Finalizes Agreement Related to Asacol® HD Patent Challenge Litigation,” available at <https://www.allergan.com/news/news/thomson-reuters/actavis-finalizes-agreement-related-to-asacol-hd-p>.

2015).²⁷²

433. On August 1, 2016, Zydus Pharmaceuticals announced it would begin selling an authorized generic version of Allergan's Asacol HD (mesalamine) 800 mg delayed-release tablets, using Asacol HD tablets supplied by Allergan.²⁷³

434. Even though publicly CVS Health has been an outspoken critic of drug maker pay-for-delay deals, privately its SSG/DNS deals actually did exactly the opposite, actually facilitating the Drug Maker's tactics.

435. For Asacol HD, shortly after Zydus began marketing the authorized generic, CVS Caremark entered into an anticompetitive "rebate wall" agreement with Allergan,²⁷⁴ requiring that SilverScript add Asacol HD added to the SSG/DNS Scheme on September 23, 2016, thus blocking elderly, ESRD and disabled SilverScript members' access to the less costly generic.

2. *SilverScript Deception Blocked Access to the Less Costly Generic Asacol HD (mesalamine-sofoamine)*

436. After Asacol HD was added to the SSG/DNS Scheme, SilverScript CCRs were provided materials and training instructing them to inform beneficiaries that:

[d]uring the initial launch phase for the generic, there will be few manufacturers marketing the generic and the cost of the generic is expected to be relatively high. To help keep out-of-pocket costs low, SilverScript is retaining brand ASACOL® HD DELAYED-RELEASE TABLETS on its formulary on Non-Preferred Drug Tier (Tier 4). SilverScript will continue to keep the brand version of ASACOL HD

²⁷² Joe Nocera, *How Allergan Continues to Make Drug Prices Insane*, Bloomberg (Jan. 9, 2018), <https://www.bloomberg.com/opinion/articles/2018-01-09/how-allergan-continues-to-make-drug-prices-insane>.

²⁷³ *Zydus to sell Asacol HD's generic in US market*, Business Standard (July 14, 2016), available at https://www.business-standard.com/article/pti-stories/zydus-to-sell-asacol-hd-s-generic-in-us-market-116071401279_1.html.

²⁷⁴ Joshua Cohen, *Rebate Walls Stifle Prescription Drug Competition*, Forbes (March 1, 2021), available at <https://www.forbes.com/sites/joshuacohen/2021/03/01/rebate-walls-stifle-prescription-drug-competition/?sh=40443b866ae9>.

DELAYED-RELEASE TABLETS on the formulary and will NOT be adding the generic version until further notice.²⁷⁵

The CCR statement about keeping out-of-pocket low was false. The generic drug option(s) were lower cost to the member and Medicare Part D than the brand.

437. They were also to tell beneficiaries that:

Retaining brand ASACOL HD DELAYED-RELEASE TABLETS on Non-Preferred Drug Tier (Tier 4) can help keep out-of-pocket costs low for SilverScript beneficiaries. Note: The generic equivalent mesalamine delayed-release tablets is not on the formulary until further notice. Beneficiaries have the option to request an exception if they wish to obtain mesalamine delayed-release tablets. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level. Brand ASACOL HD DELAYED-RELEASE TABLETS is available at the Non-Preferred Drug Tier (Tier 4) copay/coinsurance, so if the request for the generic is granted, the beneficiary would pay the amount associated with the plan's exception tier. This may be a different cost than the brand.²⁷⁶

This, too, was false. Asacol HD was at the time a Tier 4 drug. A formulary exception would also have been approved for Tier 4. Keeping the brand as the only SilverScript formulary option would not have resulted in lower out-of-pocket costs. Moreover, the exception request language was intended to discourage beneficiaries from asking for a formulary exception by using misleading terminology "highest cost share level." A formulary exception would always result in a lower beneficiary and Medicare cost for the generic mesalamine delayed-release tablets.

438. If SilverScript CCRs were asked whether Asacol HD Delayed Release Tablets would cost more in any stage for LIS beneficiaries, they were to tell them:

In the Catastrophic Coverage Stage of the benefit, you will continue to receive ASACOL HD DELAYED-RELEASE TABLETS at no cost. If you have not yet reached the Catastrophic Coverage Stage, you might have to pay your brand-name

²⁷⁵ Exhibit 23 (CVS-000272-82).

²⁷⁶ *Id.*

copayment for ASACOL HD DELAYED-RELEASE TABLETS until you reach the Catastrophic Coverage Stage.²⁷⁷

This was misleading because comparative costs are not provided to subsidy members, leaving them without information to determine actual cost differences. If they had been truthful, SilverScript CCRs would have informed LIS beneficiaries:

- The cost to LIS 1 beneficiaries in the initial coverage stage for CY2019 is \$8.50 for the brand and \$3.40 for the generic mesalamine delayed-release tablets. Beneficiaries will pay \$0 for both the brand and the generic in the Catastrophic Coverage stage.
- Medicare Part D will pay \$518.95 for the brand (\$527.45 - \$8.50) and \$344.70 for the generic mesalamine delayed-release tablets (\$348.10- \$3.40) in the ICL stage.
- Medicare Part D will pay \$321.16 for the brand (\$329.66 - \$8.50) and \$318.60 (\$322.00 - \$3.40) for the generic mesalamine delayed-release tablets in the Coverage Gap (where applicable) stage.
- Medicare Part D will pay \$65.93 for the brand and \$43.51 for the generic mesalamine delayed-release tablets in the Catastrophic Coverage stage (full amount of beneficiary's cost) in addition to 80% of the cost of either drug for the Medicare portion of the cost of the drugs in this stage.

439. If asked by beneficiaries “[w]hy is the brand-name ASACOL HD DELAYED-RELEASE TABLETS on the formulary when there is now a generic available,” they were to respond:

In this case, the price of the generic version of ASACOL HD DELAYED-RELEASE TABLETS will likely be similar to the price of the brand version for a minimum of six months, and perhaps longer. There are few manufacturers of the generic version of ASACOL HD DELAYED-RELEASE TABLETS to drive the price down. Until there are competitors and the price of the generic version goes

²⁷⁷ *Id.*

down, your plan will continue to cover brand-name ASACOL HD DELAYED-RELEASE TABLETS at the Non-Preferred Drug Tier (Tier 4) cost share in 2019.²⁷⁸

The CCR statement about how long it will take for the generic price to come down was false. The generic mesalamine 800 mg delayed-release tablets are already much lower in price for most beneficiaries. There was no need to wait for there to be multiple generic manufacturers to drive the price down.

440. If they were asked why they could not get a generic mesalamine delayed-release tablets, they were trained to respond:

When a generic version is first available, it is typically similar in price to the brand version. At this time the generic version, called mesalamine delayed-release tablets, is not on the formulary. You do have the option to request a formulary exception. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.²⁷⁹

The CCR statement about generic pricing was misleading. While this statement may have been true for newly released generics, the generic mesalamine delayed-release tablets has been on the market for almost three years and is at a lower cost option for beneficiaries. And, it was deceptive. The exception request language was intended to discourage beneficiaries from asking for a formulary exception. A formulary exception for the generic mesalamine delayed-release tablets would have been approved at the highest tier (Tier 4) which is the same tier/cost share (40%) as the brand.

441. If asked how long Asacol HD would be the only SilverScript formulary option, they were expected to tell beneficiaries:

We anticipate that ASACOL HD DELAYED-RELEASE TABLETS will remain on the formulary on the Non-Preferred Drug Tier (Tier 4) in 2019 until the price of

²⁷⁸ *Id.*

²⁷⁹ *Id.*

the generic form of ASACOL HD DELAYED-RELEASE TABLETS drops. We anticipate it will be a minimum of six months, however that is based on market conditions not within our control and could change.²⁸⁰

442. The CCR template statement about generic pricing was misleading. By February 2019, the GoodRx price of the generic mesalamine delayed-release tablets was \$240.96 compared to the price of the brand Asacol HD of \$885.91, already making the generic a lower cost option for both the beneficiary and Medicare Part D.

443. Thus, the decision to keep brand-name Asacol HD as the only choice on the SilverScript formulary was not driven by market conditions at all. Likewise, it was a lie and deceptive to say that the market conditions were not “within our control” when it was CVS Caremark’s agreement with Allergan that was the cause for the delay in the formulary access to the less costly generic drug mesalamine delayed-release tablets. The market conditions were thus completely within its control.

444. If beneficiaries asked whether they could submit a coverage determination, SilverScript CCRs were to respond: “Yes, you as the beneficiary may request a coverage determination for mesalamine delayed-release tablets. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.”²⁸¹ This was misleading and intended to discourage beneficiaries from asking for a formulary exception. A formulary exception for the generic would have been approved at the highest tier (Tier 4) which is the same tier/cost share 40% as the brand-name Asacol HD.

3. Beneficiary No. 3

445. When Beneficiary No. 3 (an 82-year-old woman living in Florida) sought to fill a

²⁸⁰ *Id.*

²⁸¹ *Id.*

prescription for the generic Asacol HD (mesalamine-sofoamine) on November 8, 2018, she was able to get the prescription filled under a tiering exception at her pharmacy.²⁸²

446. She later received a Notice of Approval letter from SilverScript telling her that her Asacol HD prescription had been approved under a tiering exception to receive Asacol HD at the copay level for a Tier 2 drug, \$17.00.²⁸³ This tiering exception was approved from August 10, 2018 to November 8, 2019. What the letter failed to tell her was that tiering exceptions only apply in the Initial Coverage Stage, and they do not allow for a lower price in the Coverage Gap (where applicable) or the Catastrophic Coverage Stage.

447. On February 9, 2019, she again filled the Asacol HD prescription at her pharmacy, again with a member copay of \$17.00.²⁸⁴

448. A month later on March 12, 2019, she attempted to fill the Asacol HD prescription again, but this time the copay had increased to \$345.73. She thereafter filed a grievance seeking the low \$17.00 copay, which was declined because the generic mesalamine was non-formulary. There is no indication from the grievance notes that the representative, Andrea Jarmon, discussed the less costly authorized generic or offered a Beneficiary No. 3 a formulary exception.²⁸⁵

449. Beneficiary No. 3 was then transferred to the Care Exception Representative (CER) team to discuss why she could no longer get the \$17.00 copay for Asacol HD. After being putting on hold and being bounced from representative to representative, she was eventually told she was

²⁸² Exhibit 24 (CVS-001712)

²⁸³ *Id.*

²⁸⁴ Exhibit 25 (CVS-001708).

²⁸⁵ Exhibit 26 (CVS-001709).

no longer eligible for the tiering exception, and should discuss other medications with her doctor in the meantime.

450. During the call, Beneficiary No. 3 had explained that she was very frustrated, particularly because she would run out of her Asacol HD prescription the following day, telling the CER she would call her doctor to discuss alternatives and asking the CER Cartier: “SilverScript is telling me ‘tough luck for my medicine beyond tomorrow,’ right?” CER Cartier confirmed on the call that her understanding was correct.²⁸⁶

451. The advice CER Cartier gave Beneficiary No. 3 is consistent with his training, which specifically instructs the CER representatives they are not proactively to advise beneficiaries of alternatives that are not on the formulary. As he had been trained to do, at no time did he tell her about the less costly authorized generic or offer her a formulary exception.

452. If a formulary exception had been offered for the authorized generic and processed as an expedited Coverage Determination, she would have been able to fill the generic with her current prescription (A/B rated authorized generic) instead of having to contact the doctor for a new prescription for one of the alternative medications.

453. In the Coverage Gap Stage, members will pay 37% for mesalamine and 25% for Asacol HD, resulting in a slightly higher cost for the member: member cost for the generic would be \$463.23 while the member cost for the brand would be \$426.51. However, when the member hits the Catastrophic Coverage stage, mesalamine-sofoamine would be less expensive than Asacol HD for both the member (who will pay 5% for either the brand or the generic) and for Medicare which will pay the balance. Given the cost of Asacol HD, Beneficiary No. 3 should progress to the Catastrophic Coverage stage after a few fills where her cost would be \$62.60, the SilverScript

²⁸⁶ Exhibit 27 (CVS-002993).

cost would be \$187.79, and the Medicare cost would be \$1001.59.

454. Illustrating that only CVS Health is the winner here (because it pockets a significant share of the brand Asacol HD rebates), since Beneficiary No. 3 was not offered the less costly authorized generic, the brand Asacol HD would cost her \$85.30, cost SilverScript \$255.90, and cost Medicare \$1364.84.

455. Furthermore, because the prescription was filled in Florida, a mandatory generic substitution State, SilverScript violated the State law requirement that the prescription be substituted with a less costly generic.

D. Renvela Packets and Tablets

456. Sevelamer carbonate is a phosphate binding drug used to treat hyperphosphatemia in patients with chronic kidney disease. Sanofi-Aventis U.S. LLC manufactures sevelamer carbonate under the brand-name Renvela.

457. In April 2009, Genzyme Corporation (the manufacturer of Renvela, which was later acquired by Sanofi) filed suit against Impax Laboratories, alleging patent infringement for the filing of the its ANDA relating to Sevelamer Carbonate Tablets, 800 mg, generic to Renvela®.

458. On July 2, 2010, Genzyme filed suit against Impax a second time, this time alleging patent infringement of its patents relating to Sevelamer Carbonate Powder, 2.4 g and 0.8 g packets.

459. On September 4, 2012, Impax announced that it had settled the patent infringement litigation with Genzyme,²⁸⁷ and would commence shipment of the authorized generic of Sanofi's drug Renvela 400 mg and 800 mg tablets as well as the generic oral suspension version of Renvela

²⁸⁷ *Impax Laboratories Announces Settlement of Litigation Relating to RENVELA® and RENAGEL®*, Fierce Pharma (Sept. 4, 2012), <https://www.fiercepharma.com/pharma/impax-laboratories-announces-settlement-of-litigation-relating-to-renvela%C2%AE-and-renagel%C2%AE>.

packets beginning on September 16, 2014.²⁸⁸ Under the terms of the settlement, Impax would continue to pursue its pending ANDAs for generic Renvela with the FDA.

460. Impax at the time stated the authorized generics to Renvela would be manufactured by a division of Sanofi: “[A]n **authorized generic drug is the exact same in all aspects as a brand-name drug**, except that it is marketed without the brand-name on its label. Choosing Winthrop US sevelamer carbonate ensures that you will get **the exact same drug product as branded Renvela**. Winthrop US’s [a division of Sanofi Aventis] sevelamer carbonate uses the same manufacturing process as Renvela. It is identical to Renvela in shape, active ingredients, size, and inactive ingredients.”²⁸⁹

461. Likewise, Sanofi-Aventis’ subsidiary Winthrop US includes a chart on its website²⁹⁰ to show that the authorized generic “is identical” to the brand Renvela “in shape, active ingredients, size, and inactive ingredients”:

Winthrop US's sevelamer carbonate uses the same manufacturing process as Renvela. It is identical to Renvela in shape, active ingredients, size, and inactive ingredients.

	Renvela	VS	Sevelamer carbonate Authorized Generic
Picture may not depict actual size.			
Active Ingredients	✓		✓
Inactive Ingredients	✓		✓
Shape	✓		✓
Manufacturing Process	✓		✓
Size (19mm)	✓		✓
Raw Material Sourcing	✓		✓
Manufacturing Consistency	✓		✓

²⁸⁸ PRNewswire, “Impax Launches Authorized Generic RENVELA®” available at <https://www.prnewswire.com/news-releases/impax-launches-authorized-generic-renvela-255473571.html> (last accessed June 6, 2019).

²⁸⁹ “Sevelamer carbonate—the authorized generic identical to Renvela®” available at <http://www.renvela.com/authorized-generic> (last accessed June 6, 2019) (emphasis added).

²⁹⁰ See <https://www.renvela.com/authorized-generic>.

462. Despite the loss of Renvela exclusivity, in its 2016 Form 20-F, Sanofi-Aventis announced sales of Renvela actually had risen by 18.9%, “reflecting reduced competition from Impax which for a few months beginning April 2014 had the right to sell a limited number of authorized generics of Renvela.”

463. For the 12 months ended July 2017, the drug had U.S. sales of roughly \$1.88 billion.

464. On October 2, 2017, Dr. Reddy’s announced launched Sevelamer Carbonate Tablets, 800 mg, a therapeutic equivalent generic version of Renvela tablets, approved by the FDA.²⁹¹

465. On October 23, 2017, Impax announced it had received final FDA approval on its ANDA for a generic version of Renvela tablets, 800 mg and would immediately initiate commercialization activities.²⁹²

466. Shortly before, CVS Caremark had entered into an agreement with Sanofi-Aventis, requiring that SilverScript add Renvela Packets to the SSG/DNS Scheme on August 1, 2017 and Renvela Tablets to the SSG/DNS Scheme on August 22, 2017.

1. CVS Blocked Access to the Less Costly Generic Version of the Brand-Name Renvela Packets (sevelamer carbonate)

467. After Renvela Packets were added to the SSG/DNS Scheme, SilverScript CCRs were trained to tell beneficiaries:

²⁹¹ *Dr. Reddy’s Laboratories announces the launch of sevelamer carbonate tablets in the U.S. market*, Pharmaceutical Processing World (Oct. 2, 2017), <https://www.pharmaceuticalprocessingworld.com/dr-reddys-launches-generic-version-of-genzyme-corp-s-renvela-in-u-s/>.

²⁹² Press Release, *Impax Announces FDA Approval and Launch of Generic Renvela® (Sevelamer Carbonate) Tablets, 800 mg* (Oct. 23, 2017), <https://www.prnewswire.com/news-releases/impax-announces-fda-approval-and-launch-of-generic-renvela-sevelamer-carbonate-tablets-800-mg-300541365.html>.

Generic prescription drugs are typically the lowest-cost option when compared to branded prescription drugs. SilverScript promotes the use of generic prescription drugs to help plan beneficiaries save money. During the initial launch phase for the generic, there will be few manufacturers marketing the generic and the cost of the generic is expected to be relatively high. To help keep out-of-pocket costs low, SilverScript is retaining brand RENVELA ORAL PACKETS on its formulary on Preferred Brand Tier (Tier 3). RENVELA is eligible for a manufacturer discount in the coverage gap.²⁹³

The is misleading. Authorized generics are eligible for the Coverage Gap discount program since they are NDA “applicable” drugs.²⁹⁴ The generic sevelamer carbonate option(s) were lower cost to the member and Medicare than the brand for LIS (subsidized) members across all “applicable” stages and for non-subsidized members in the SilverScript Allure Plan in the ICL stage and for all SilverScript plans in the Coverage Gap (where applicable) and Catastrophic Coverage Stage. Moreover, given the fact that in addition to Sanofi’s authorized generic there were as of 2019 two competing generics (Aurobindo, Dr. Reddys), there was simply no longer any reasonable explanation why Renvela Packets remained the only SilverScript formulary option.

468. SilverScript CCRs were also trained to tell beneficiaries:

Retaining brand RENVELA ORAL PACKETS on Preferred Brand Tier (Tier 3) can help keep out-of-pocket costs low for SilverScript beneficiaries. . . . Beneficiaries have the option to request an exception if they wish to obtain sevelamer carbonate oral packets. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level. Brand RENVELA ORAL PACKETS is available at the Preferred Brand Tier (Tier 3) copay/coinsurance, so if the request for the generic is granted, the beneficiary would pay the amount associated with the plan’s exception tier. This may be a different cost than the brand.²⁹⁵

²⁹³ Exhibit 28 (CVS-000220-29).

²⁹⁴ CMS, *Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance* (May 21, 2010), at 4.

²⁹⁵ *Id.*

This was misleading. Renvela Oral Packets was at the time a Tier 3 drug. A formulary exception would have been approved for Tier 4. This would result in a higher cost for the generic in the ICL stage only (Choice, Plus) and a lower cost for the generic (Allure). For the Coverage Gap and Catastrophic Coverage Stages, the generic would be less expensive in all plans. Generic would be less expensive than the brand for LIS (subsidized) members in all stages. Moreover, given the fact that in addition to the authorized generic there were as of 2019 five competing generics (Actavis, Amneal, Inventia, Mylan, Sun), there was simply no longer any reasonable explanation why Renvela Packets remain the only SilverScript formulary option.

469. If asked whether Renvela Oral Packets would cost more than the generic in any coverage stage of the Medicare Part D benefit, SilverScript CCRs were to tell LIS beneficiaries: “In the Catastrophic Coverage Stage of the benefit, you will continue to receive RENVELA ORAL PACKETS at no cost. If you have not yet reached the Catastrophic Coverage Stage, you might have to pay your brand-name copayment for RENVELA ORAL PACKETS until you reach the Catastrophic Coverage Stage.”²⁹⁶ This was misleading. Costs are not provided leaving subsidy beneficiaries without information to determine the actual impact. If they had provided truthful information to LIS beneficiaries, SilverScript CCRs would have told them:

- The cost to LIS 1 beneficiaries in initial coverage stage for CY2019 is \$8.50 for the brand and \$3.40 for the generic. Beneficiaries will pay \$0 for both the brand and the generic sevelamer carbonate oral packets in the Catastrophic Coverage stage.
- Medicare will pay \$26.50 for the brand (\$35.00 - \$8.50) and \$158.19 for the generic sevelamer carbonate oral packets (\$161.59 - \$3.40) in the ICL stage.

²⁹⁶ *Id.*

- Medicare will pay \$388.86 for the brand (\$397.36 - \$8.50) and \$146.07 (\$149.47 - \$3.40) for the generic sevelamer carbonate oral packets in the Coverage Gap (where applicable).
- Medicare will pay \$79.47 for the brand and \$20.20 for the generic sevelamer carbonate oral packets in the Catastrophic Coverage stage (full amount of beneficiary's cost) in addition to 80% of the cost of either drug for the Medicare portion of the cost of the drugs in this stage.

470. If asked why Renvela Oral Packets remain the exclusive formulary choice when there is a generic available, they were to tell beneficiaries:

In this case, the price of the generic version of RENVELA ORAL PACKETS will likely be similar to the price of the brand version for a minimum of six months, and perhaps longer. There are few manufacturers of the generic version of RENVELA ORAL PACKETS to drive the price down. Until there are competitors and the price of the generic version goes down, your plan will continue to cover brand-name RENVELA at the Preferred Brand Tier (Tier 3) copay/coinsurance in 2018 and 2019.²⁹⁷

This was false. The generic sevelamer carbonate oral packets was, in fact, already much lower in price for many beneficiaries in the Coverage Gap (where applicable) and Catastrophic Coverage Stages. There was no need to wait for there to be multiple generic manufacturers to drive the price down.

471. If SilverScript CCRs were asked by beneficiaries why they could not get the generic sevelamer carbonate oral packets, according to their training they were to respond:

When a generic version is first available, it is typically similar in price to the brand version. At this time the generic version, called sevelamer carbonate oral packets, is not on the formulary. You do have the option to request a formulary exception. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.²⁹⁸

²⁹⁷ *Id.*

²⁹⁸ *Id.*

The statement about generic pricing was misleading. While this statement may have been true for some newly released generics, the generic sevelamer carbonate oral packets was already much lower in price for some beneficiaries in the ICL stage and all beneficiaries in the Coverage Gap (where applicable) and Catastrophic Coverage Stages. There was no need to wait for there to be multiple generic manufacturers for the price to be lower. The statement about the formulary exception was intended to discourage beneficiaries from asking for a formulary exception when the generic would be less expensive for many subsidy members in the Choice plan and all members in the Allure plan.

472. If asked how long Renvela Packets would remain the only SilverScript formulary option, they were to say: “We anticipate that RENVELA ORAL PACKETS will remain on the formulary on the Preferred Brand Tier (Tier 3) in 2018 and 2019 until the price of the generic form of RENVELA drops. We anticipate it will be a minimum of six months, however that is based on market conditions not within our control and could change.”²⁹⁹

473. This was misleading. By February 2019, the GoodRx price of the generic was \$403.98 compared to the brand Renvela Oral Packets price of \$1,589.42, already making the generic a lower cost option for both the beneficiary and Medicare.

474. Thus, the decision to keep the brand Renvela Oral Packets as the only choice on the SilverScript formulary was not driven by market conditions, but by CVS Health’s own profit motives. This was even more deceptive in 2020, well past the promised price drop related to “market conditions.”³⁰⁰ There were then two generics (beyond the authorized generic) being sold

²⁹⁹ *Id.*

³⁰⁰ *Id.*

competing against Renvela Packets (Aurobindo, Dr. Reddys). Even then the brand-name Renvela Packets remained the only choice on the SilverScript Choice and Plus formularies.³⁰¹ Likewise, it was a lie and deceptive to say that the market conditions were not “within our control” when it was CVS Caremark’s agreement with Sanofi that was the cause for the delay in the formulary access to the less costly generic drug sevelamer carbonate oral packets. The market conditions were thus completely within its control.

475. If asked whether beneficiaries could obtain a coverage determination for the generic sevelamer carbonate oral packets, SilverScript CCRs were to tell beneficiaries: “Yes, you as the beneficiary may request a coverage determination for sevelamer carbonate oral packets. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.”³⁰² This was misleading and was intended to discourage beneficiaries from asking for a formulary exception.

2. SilverScript Deception Blocked Access to the Less Costly Generic for the Brand-Name Renvela Tablets

476. After Renvela Tablets were added to the SSG/DNS Scheme, SilverScript CCRs were told to tell beneficiaries:

Generic prescription drugs are typically the lowest-cost option when compared to branded prescription drugs. SilverScript promotes the use of generic prescription drugs to help plan beneficiaries save money. During the initial launch phase for the generic, there will be few manufacturers marketing the generic and the cost of the generic is expected to be relatively high. To help keep out-of-pocket costs low, SilverScript is retaining brand RENVELA TABLETS on its formulary on Preferred

³⁰¹ See 2020 SilverScript Choice Comprehensive Formulary, available at https://www.silverscript.com/pdf/FORM_2020_CHOICE_EN.pdf; 2020 SilverScript Plus Comprehensive Formulary, available at https://www.silverscript.com/pdf/FORM_2020_PLUS_EN.pdf.

³⁰² *Id.*

Brand Tier (Tier 3). RENVELA TABLETS is eligible for a manufacturer discount in the coverage gap.³⁰³

This is misleading. Authorized generics are eligible for the Coverage Gap discount program since they are NDA “applicable” drugs.³⁰⁴ The generic drug option(s) were lower cost to the member and Medicare in most scenarios in the Coverage Gap (where applicable) and the Catastrophic Coverage Stages.

477. SilverScript CCRs were also trained to say:

Retaining brand RENVELA TABLETS on Preferred Brand Tier (Tier 3) can help keep out-of-pocket costs low for SilverScript beneficiaries. Beneficiaries have the option to request an exception if they wish to obtain sevelamer carbonate tablets. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.³⁰⁵

This was false. Keeping the brand as the only option would not have resulted in lower out-of-pocket costs for most beneficiaries and Medicare in the Coverage Gap (where applicable) and Catastrophic Coverage Stages. It also intentionally is meant to discourage beneficiaries from asking for a formulary exception by using the language “highest cost share level.”

478. If SilverScript CCRs were asked whether Renvela Tablets would cost more than the generic at any stage of the Medicare Part D benefit, they were to tell subsidy members:

Maybe. In the Catastrophic Coverage Stage of the benefit, you will continue to receive RENVELA TABLETS at no cost. If you have not yet reached the Catastrophic Coverage Stage, you might have to pay your brand-name copayment for RENVELA TABLETS until you reach the Catastrophic Coverage Stage.³⁰⁶

³⁰³ Exhibit 29 (CVS-000241-51).

³⁰⁴ CMS, *Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance* (May 21, 2010), at 4.

³⁰⁵ *Id.*

³⁰⁶ *Id.*

This was deceptive because cost comparisons are not provided, leaving beneficiaries without information to determine the actual impact. If they had been directed to provide truthful information, SilverScript CCRs would have told LIS beneficiaries: The cost to LIS 1/LIS 2 beneficiaries in the initial coverage stage for CY2019 is \$8.50/\$3.80 for the brand and \$3.40/\$1.25 for the generic. Beneficiaries will pay \$0 for both the brand and the generic in the Catastrophic Coverage stage. In ICL for LIS 1 & 2 in 2019, the brand would have been less expensive for Medicare. In the Coverage Gap (where applicable) and Catastrophic coverage scenarios for LIS 1 & 2 in 2019, the generic would have been less expensive for the beneficiary and Medicare.

479. When beneficiaries inquired about why Renvela Tablets were still the only SilverScript formulary option when there is a generic available, the response they were directed to provide was:

In this case, the price of the generic version of RENVELA TABLETS will likely be similar to the price of the brand version for a minimum of six months, and perhaps longer. There are few manufacturers of the generic version of RENVELA TABLETS to drive the price down. Until there are competitors and the price of the generic version goes down, your plan will continue to cover brand-name RENVELA TABLETS at the Preferred Brand Tier (Tier 3) copay/coinsurance in <2018 and 2019>.³⁰⁷

This was false. The generic sevelamer carbonate tablets was, in fact, already much lower in price for many beneficiaries in the Coverage Gap (where applicable) and Catastrophic Coverage Stages.

There was no need to wait for there to be multiple generic manufacturers to drive the price down.

480. When beneficiaries asked why they could not get the generic, SilverScript told them to say:

When a generic version is first available, it is typically similar in price to the brand version. At this time the generic version, called sevelamer carbonate tablets, is not on the formulary. You do have the option to request a formulary exception.

³⁰⁷ *Id.*

However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.³⁰⁸

This was misleading. While this statement may have been true for some newly released generics, the generic was already much lower in price for some beneficiaries in the ICL stage and most beneficiaries in the Coverage Gap (where applicable) and Catastrophic Coverage Stages. There was no need to wait for there to be multiple generic manufacturers. It was intended to discourage beneficiaries from asking for a formulary exception where the generic would be less expensive for many subsidy members in the Choice plan and all members in the Allure plan.

481. If asked how long Renvela Tablets would be the only option on the SilverScript formulary, the response was deceptive: “We anticipate that RENVELA TABLETS will remain on the formulary on the Preferred Brand Tier (Tier 3) in 2018 and 2019 until the price of the generic form of RENVELA TABLETS drops. We anticipate it will be a minimum of six months, however that is based on market conditions not within our control and could change.”³⁰⁹

482. This was misleading. As of February 2019, the GoodRx price of the generic was \$135.65 compared to the brand Renvela Tablets price of \$540.35, already making the generic a lower cost option for both the beneficiary and Medicare Part D in the Coverage Gap (where applicable) and Catastrophic Coverage Stages.

483. The decision to keep the brand Renvela Tablets as the only choice on the SilverScript formulary was not driven by market conditions, but by CVS Health’s own profit motives. This was even more deceptive by 2020, well past the promised price drop related to “market conditions.” There were then eight generics being sold competing against Renvela Tablets

³⁰⁸ *Id.*

³⁰⁹ *Id.*

(Amneal, Anxin, Aurobindo, Dr. Reddys, Impax, Invagen, TWI, Wilshire). However, even then the brand-name Renvela Tablets remained the only choice on the SilverScript Choice and Plus formularies.³¹⁰ Likewise, it was a lie and deceptive to say that the market conditions were not “within our control” when it was CVS Caremark’s agreement with Sanofi that was the cause for the delay in the formulary access to the less costly generic drug sevelamer carbonate tablets. The market conditions were thus completely within its control.

484. If beneficiaries asked whether they could request a coverage determination for the less costly generic, the response was deceptive: “Yes, you as the beneficiary may request a coverage determination for sevelamer carbonate tablets. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.”³¹¹ The use of “highest cost share level” was intended to discourage beneficiaries from asking for a formulary exception which would help reduce the cost of the generic vs the brand in the Coverage Gap (where applicable) and Catastrophic Coverage Stages.

3. Beneficiary No. 4

485. When Beneficiary No. 4 (a 66-year-old man living in Kentucky) sought to fill a prescription for the generic Renvela (sevelamer carbonate tablets) on September 20, 2018, he was able to get his prescription with a Transition Fill at his pharmacy.

486. Shortly thereafter, he received a letter from SilverScript dated September 24, 2018, stating that the Transition Fill of the generic was only a one-time fill because the drug was not

³¹⁰ See 2020 SilverScript Choice Comprehensive Formulary, available at https://www.silverscript.com/pdf/FORM_2020_CHOICE_EN.pdf; 2020 SilverScript Plus Comprehensive Formulary, available at https://www.silverscript.com/pdf/FORM_2020_PLUS_EN.pdf.

³¹¹ Exhibit 29 (CVS-000241).

covered on the formulary, and he was required to use the brand Renvela 800 mg tablets thereafter.³¹² SilverScript failed to notify Beneficiary No. 4 that there was an identical, less costly authorized generic for the brand Renvela.

487. He later received a Notice of Approval letter from SilverScript dated October 2, 2018, telling him that his generic sevelamer carbonate tablet prescription had been approved under a tiering exception. This tiering exception was approved from September 1, 2019 through October 2, 2019.³¹³ SilverScript again failed to notify Beneficiary No. 4 that there was an identical, less costly authorized generic for the brand Renvela. The letter also failed to tell him that tiering exceptions only apply in the Initial Coverage Stage, and they do not allow for a lower price in the Coverage Gap (where applicable) Stage or the Catastrophic Coverage Stage.

488. Beneficiary No. 4, thereafter filled the sevelamer carbonate prescription at the pharmacy. The claim record shows that the pharmacy filled his sevelamer prescription and submitted the claims with a “0 – NO DAW” code.³¹⁴

489. When he later learned that the tiering exception would not apply when he was in the Donut Hole, he then filled the Renvela prescription. The claim record shows that the CVS Pharmacy filled his prescription and submitted the claims with a “1 – PHYSICIAN DAW” code, meaning the physician requested the brand.³¹⁵

490. Here, as evidenced by Beneficiary No. 4’s prior use of the generic sevelamer carbonate tablets, there is little reason to believe his physician had actually stated it was medically

³¹² Exhibit 30 (CVS-002679).

³¹³ Exhibit 31 (CVS-002675).

³¹⁴ Exhibit 32 (CVS-002678).

³¹⁵ Exhibit 33 (CVS-002677).

necessary for him to use the brand Renvela instead of the generic, but was required to choose the brand only because CVS Health did not include the generic on its formulary. Thus, a DAW 1 code in the PDE record in support of the SilverScript payment for Beneficiary No. 4 appears to be untruthful, inaccurate and incomplete.

491. The decision to require Beneficiary No. 4 to use the brand drove up the costs for both the Government and Beneficiary No. 4. At the time, the total plan cost of the generic was \$170.70 while the total plan cost of Renvela was \$989.54, a 579% increase in cost. While the copayment for Beneficiary No. 4 was \$119.80 for the generic sevelamer carbonate and for \$35.00 for Renvela, the high cost of Renvela would drive him into the Catastrophic Coverage Stage sooner, where both the Beneficiary No. 4's copay and the Government's cost would be much greater than it would have been for the generic.

492. Not only had SilverScript inexplicably reversed the tiering exception he had been offered, at no time was he offered the authorized generic, which would have been less costly for Beneficiary No. 4 and the Government.

E. Harvoni/Epclusa

493. Ledipasvir/SofosBuvir is a fixed-dose combination of ledipasvir, a hepatitis C virus (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and is indicated for the treatment of chronic hepatitis C virus (HCV) in adults with genotype 1, 4, 5, or 6 infection. Gilead Sciences, Inc. manufactures Ledipasvir/SofosBuvir under the brand-name Harvoni.

494. Sofosbuvir/Velpatasvir is a fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, and velpatasvir, an HCV NS5A inhibitor, and is indicated for the treatment of adult patients with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection. Gilead Sciences, Inc. manufactures Sofosbuvir/Velpatasvir under the brand-

name Epclusa.

495. Asegua Therapeutics was formed in 2018 by Gilead as a wholly owned subsidiary to provide “greater access to therapies.”³¹⁶ On September 24, 2018, Gilead announced that Asegua would launch authorized generic versions of Harvoni and Epclusa.³¹⁷ On November 27, 2018, Asegua launched an authorized generic version of Epclusa and on January 1, 2019, Asegua launched an authorized generic versions of Harvoni.³¹⁸

496. At the time, Gilead claimed that “dynamic and complicated insurance contracts were the reason it was forming a new business unit to offer versions of the drug at lower list prices.”³¹⁹ According to the press release Gilead issued at the time: “Due to the complexity and structure of the U.S. healthcare system, however, these discounts provided by Gilead **may not always translate into lower costs for patients. Further, existing contracts, together with laws associated with government pricing policies, make it challenging to quickly lower a product’s list price once it is on the market.**”³²⁰ (emphasis added)

³¹⁶ “Authorized Generic Hepatitis C Drugs & Treatment: Asegua Therapeutics,” <https://www.asegua.com>.

³¹⁷ *Id.*

³¹⁸ Silverman, “Looking to bolster dwindling hepatitis C sales, Gilead plans to sell generic versions,” *Pharmalot*, Sept. 24, 2018, available at <https://www.statnews.com/pharmalot/2018/09/24/gilead-hepatitis-authorized-generics/>.

³¹⁹ Spalding, “Gilead to Sell Less Costly Versions of Drug That Sparked Cost Debate,” *Bloomberg*, Sept. 24, 2018, available at <https://www.bloomberg.com/news/articles/2018-09-24/gilead-to-sell-less-costly-versions-of-drug-that-sparked-cost-debate>.

³²⁰ Press Release, “Gilead Subsidiary to Launch Authorized Generics of Epclusa® (Sofosbuvir/Velpatasvir) and Harvoni® (Ledipasvir/SofosBuvir) for the Treatment of Chronic Hepatitis C,” Sept. 24, 2018, available at <https://www.gilead.com/news-and-press/press-room/press-releases/2018/9/gilead-subsidiary-to-launch-authorized-generics-of-epclusa-sofosbuvirvelpatasvir-and-harvoni-ledipasvirsofosbuvir-for-the-treatment-of-chronic>.

497. CVS Caremark shortly thereafter entered into an agreement with Gilead, requiring that SilverScript add Epclusa to the SSG/DNS Scheme on November 27, 2018³²¹ and add Harvoni to the SSG/DNS Scheme on January 1, 2019.

498. The fraudulent SSG/DNS Scheme's ethical low point came with the 2018 decision to apply it to Gilead's brand-name hepatitis C drugs Harvoni and Epclusa where CVS Health Executive Committee leadership had deemed the fact that some 84% of SilverScript beneficiaries were receiving the LIS subsidy meant the risk of detection by CMS was relatively low.

499. The fact that a high percentage of SilverScript beneficiaries have their cost-sharing subsidized by Medicare (and who were therefore highly unlikely to complain about the SSG/DNS Scheme) has only emboldened CVS Health leadership to expand its efforts to block generic versions of medications and instead fill only the more expensive brand-name options.

500. As part of its agreement with Gilead regarding Harvoni and Epclusa, CVS Caremark agreed to require SilverScript to adopt an explicit policy to go beyond just deceiving SilverScript beneficiaries about the cost of the authorized generic drugs. Instead, SilverScript was required to deny any and all formulary exceptions and appeals for the less costly authorized generic versions. And, were that not enough, the CVS Caremark agreement with Gilead required that the CVS Pharmacies would no longer stock the authorized generic versions of Harvoni and Epclusa on their shelves. This has meant not only that the authorized generics for Harvoni and Epclusa were unavailable to SilverScript beneficiaries who fill scripts at the CVS Pharmacies, but also would not have been available to the 45 million Part D beneficiaries, many of whom would have filled their prescriptions at a CVS Pharmacy.

³²¹ *Id.*

501. The SSG/DNS Scheme blocking strategy is particularly insidious for very expensive drugs like the drugs Harvoni and Epclusa. For each of the three treatments patients received with these drugs, Harvoni costs around \$32,127.27 per treatment and Epclusa costs around \$25,184.05 per treatment. The authorized generic versions cost over 300% less per treatment: approximately \$12,265.92 for ledipasvir-sofosbuvir (generic Harvoni) and \$8,083.20 for sofosbuvir-velpatasvir (generic Epclusa).

502. Despite public statements by CVS Health about favoring access to less costly generics, in reality it pursued its own bottom line over cost savings to Medicare and Part D beneficiaries, particularly for Harvoni and Epclusa which had together an average of 1604 SilverScript claims each month.

503. The SSG Harvoni/Epclusa strategy was very controversial within the walls of the company. Even though its Executive Committee had approved the scheme because the financial benefit to the company was simply too tempting to pass up, some in CVS Health senior management (including the Relator) complained that it was “highly unethical.” For example, CVS Health Vice President of Medicare Operations Emily Pefanis complained of this in multiple conversations with Amy Moyer-Carey, CVS Health Vice President Coverage Determinations. Even though Moyer-Carey was reportedly “sick over this,” she was told by Mitch Betses (CVS Health Executive Vice President, Member Services), Todd Meek (President of SilverScript), and Patrick Jeswald (CVS Health Chief Compliance Officer, Medicare Part D) that they were to do this, nonetheless.

504. The first year of the SSG Harvoni/Epclusa Scheme shows how CVS Health had no intention of actually passing through to the beneficiaries and Medicare any of the manufacturer rebates for those drugs. Medicare requires Prescription Drug Programs (“PDPs”) such as

SilverScript who wish to enter into contracts to offer prescription drug coverage to submit bids over the summer before the next plan year (*e.g.*, for plan year 2020 the bids are due in June 2019). The PDP applications include information about plan design, premium costs, and the value of rebates. Yet, the authorized generic versions of Harvoni and Epclusa were not announced until September of 2018, well after the SilverScript bid was submitted for the following year. This means that SilverScript could not have included in its information provided to CMS the value of any rebates from Gilead in its 2019 PDP design and costs.

1. SilverScript Deception Blocked Access to the Less Costly Generic for the Brand-Name Epclusa

505. At the time the Epclusa SSG/DNS Scheme was initiated, SilverScript CCRs were provided materials and training telling them that they should explain to beneficiaries that

[r]etaining brand EPCLUSA TABLETS on Specialty Tier (Tier 5) can help keep out-of-pocket costs low for SilverScript beneficiaries. NOTE: The generic equivalent sofosbuvir/velpatasvir 400MG-100MG tablets is not on the formulary until further notice. Beneficiaries have the option to request an exception if they wish to obtain sofosbuvir/velpatasvir 400MG-100MG tablets. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level. Brand EPCLUSA TABLETS is available at the Specialty Tier (Tier 5) copay/coinsurance, so if the request for the generic is granted, the beneficiary would pay the amount associated with the Part D plan's exception tier. This may be a different cost than the brand.³²²

The stated rationale for keeping “out-of-pocket costs low” was false and deceptive. Epclusa was at the time a Tier 5 drug with coinsurance of 33%. A formulary exception would have been approved for Tier 4 with a generic coinsurance of 40%. Even with the higher percentage copayment, the generic sofosbuvir/ velpatasvir 400MG-100MG tablets is still less costly. Keeping the brand Epclusa as the only SilverScript formulary option would not have resulted in lower out-of-pocket costs. In addition, telling beneficiaries that a formulary exception may result in higher

³²² Exhibit 34 (CVS-000476-87).

costs is meant to discourage them from asking for a formulary exception by using misleading terminology ‘highest cost share level.’ Moreover, it was deceptive to fail to tell them that, even if beneficiaries request formulary exceptions, CVS has put into place a “block” where these requests would be automatically denied. Likewise, even with the higher coinsurance for the generic exception, due to the dramatic difference in drug pricing the generic sofosbuvir/velpatasvir 400MG-100MG tablets will always be less expensive.

506. If SilverScript CCRs were asked “[w]ill EPCLUSA TABLETS cost more than sofosbuvir/velpatasvir 400MG-100MG tablets in any stage of the Medicare D benefit,” they were to say: “This will vary based on your Plan and which Medicare Part D coverage stage you currently are in (e.g., Deductible, Initial Coverage Limits, Coverage Gap or Catastrophic).”³²³ For LIS beneficiaries, SilverScript CCRs were to say “Maybe. In the Catastrophic Coverage Stage of the benefit, you will continue to receive EPCLUSA TABLETS at no cost. If you have not yet reached the Catastrophic Coverage Stage, you might have to pay your brand-name copayment for EPCLUSA TABLETS until you reach the Catastrophic Coverage Stage.”³²⁴ This was misleading. Costs are not provided to subsidy members, leaving them without information to determine the actual impact. Had SilverScript CCRs been truthful, they would have been trained to tell LIS beneficiaries:

- The cost to LIS 1 beneficiaries in the initial coverage stage for CY2019 is \$8.50 for the brand and \$3.40 for the generic sofosbuvir/velpatasvir 400MG-100MG tablets. Beneficiaries will pay \$0 for both the brand and the generic in the Catastrophic Coverage stage.

³²³ *Id.*

³²⁴ *Id.*

- Medicare Part D will pay \$7,998.43 for the brand (\$8,006.93 - \$8.50) and \$3,277.90 for the generic sofosbuvir/velpatasvir 400MG-100MG tablets (\$3,281.30 - \$3.40) in the ICL stage.
- Medicare Part D will pay \$6,057.32 for the brand (\$6,065.85 - \$8.50) and \$3,031.81 for the generic sofosbuvir/velpatasvir 400MG-100MG tablets (\$3,035.21 - \$3.40) for the generic in the Coverage Gap (where applicable).
- Medicare Part D will pay \$1,213.17 for the brand and \$410.16 for the generic sofosbuvir/velpatasvir 400MG-100MG tablets in the Catastrophic Coverage stage (full amount of beneficiary's cost) in addition to 80% of the cost of either drug for the Medicare portion of the cost of the drugs in this stage.

507. If SilverScript CCRs were asked by beneficiaries “[w]hy is the brand-name EPCLUSA TABLETS on the formulary when there is now a generic available,” they were trained to say:

In this case, the price of the generic version of EPCLUSA TABLETS will likely be similar to the price of the brand version for a minimum of six months, and perhaps longer. There are few manufacturers of the generic version of EPCLUSA TABLETS to drive the price down. Until there are competitors and the price of the generic version goes down, your plan will continue to cover brand-name EPCLUSA TABLETS at the Specialty Tier (Tier 5) cost share in 2018 and 2019.³²⁵

The CCR statement about how long it will take for the generic price to come down was false. The generic sofosbuvir/velpatasvir 400MG-100MG tablets was, in fact, already much lower in price for most beneficiaries. There was no need to wait for there to be multiple generic manufacturers to drive the price down.

508. If SilverScript CCRs were asked “[w]hy can’t I get the generic? Aren’t generics

³²⁵ *Id.*

less expensive,” they were trained to respond:

When a generic version is first available, it is typically similar in price to the brand version. At this time the generic version, called sofosbuvir/velpatasvir 400MG-100MG tablets, is not on the formulary. You do have the option to request a formulary exception. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.”³²⁶

The CCR statement about the generic typically being at a similar price to the brand was misleading. While this statement may have been true for some newly released generics, the generic sofosbuvir/velpatasvir 400MG-100MG tablets was already at a lower cost option for beneficiaries. Moreover, the statement about exception requests was intended to discourage beneficiaries from asking for a formulary exception. A formulary exception for the generic sofosbuvir/velpatasvir 400MG-100MG tablets would have been approved at the highest tier (Tier 4) with a coinsurance of 40%. However, even with the higher coinsurance, the generic is much less expensive than the brand due to the dramatic difference in price. Adding insult to injury, in the case of Epclusa, CVS Health has taken the extra step to automatically deny any formulary exception requests, something CVS Health fails to mention here.

509. If SilverScript CCRs were asked how long Epclusa Tablets would remain on the formulary on Specialty Tier (Tier 5), they expected to respond: “We anticipate that EPCLUSA TABLETS will remain on the formulary on the Specialty Tier (Tier 5) in 2018 and 2019 until the price of the generic form of EPCLUSA TABLETS drops. We anticipate it will be a minimum of six months, however that is based on market conditions not within our control and could change.”³²⁷

³²⁶ *Id.*

³²⁷ *Id.*

510. The CCR statement about generic pricing was misleading. By February 2019, the GoodRx price of the generic was \$8,083.79 compared to the brand Epclusa price of \$25,184.05, already making the generic a lower cost option for both the beneficiary and Medicare Part D.

511. Thus, the decision to keep the brand Epclusa as the only choice on the SilverScript formulary was not driven by “market conditions,” but by CVS Health’s own profit motives. Likewise, it was a lie and deceptive to say that the market conditions were not “within our control” when it was CVS Caremark’s agreement with Gilead that was the cause for the delay in the formulary access to the less costly generic drug sofosbuvir/velpatasvir 400MG-100MG tablets. The market conditions were thus completely within its control.

512. If asked whether the beneficiary could request a coverage determination for the generic, they were to say: “Yes, you as the beneficiary may request a coverage determination for sofosbuvir/velpatasvir 400MG-100MG tablets. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.”³²⁸ The exception request statement was misleading and intended to discourage beneficiaries from asking for a formulary exception. A formulary exception for the generic would have been approved at the highest tier (Tier 4) with a coinsurance of 40%. However, even with the higher coinsurance, the generic is much less expensive than the brand-name Epclusa due to the dramatic difference in price. It was also deceptive. What beneficiaries were not to be told is that, in the case of Epclusa, CVS has taken the extra step to automatically deny any formulary exception requests.

³²⁸ *Id.*

2. *SilverScript Deception Blocked Access to the Less Costly Generic for the Brand-Name Harvoni*

513. SilverScript CCRs were to explain to beneficiaries, “[t]o help keep out-of-pocket costs low, SilverScript is retaining brand HARVONI® TABLETS on its formulary on Specialty Tier (Tier 5). HARVONI is eligible for a manufacturer discount in the coverage gap.”³²⁹ This is misleading. Authorized generics are eligible for the Coverage Gap discount program since they are NDA “applicable” drugs.³³⁰ Likewise, the rationale of keeping “out-of-pocket costs low” was false. The generic drug option ledipasvir/sofosbuvir 90MG-400MG tablets was already much lower cost to the member and Medicare Part D than the brand-name Harvoni.

514. SilverScript CCRs were also told that they should tell beneficiaries that “[r]etaining brand HARVONI TABLETS on Specialty Tier (Tier 5) can help keep out-of-pocket costs low for SilverScript beneficiaries.”³³¹ This, too, was false. Keeping the brand Harvoni as the exclusive formulary choice would not have resulted in lower out-of-pocket costs.

515. SilverScript CCRs were told to tell SilverScript beneficiaries that they “have the option to request an exception if they wish to obtain ledipasvir/sofosbuvir 90MG-400 MG tablets. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.”³³² This was deceptive and is meant to discourage beneficiaries from asking for a formulary exception by using misleading terminology

³²⁹ Exhibit 35 (CVS-000210-19).

³³⁰ CMS, *Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance* (May 21, 2010), at 4.

³³¹ Exhibit 35 (CVS-000210-19).

³³² *Id.*

“highest cost share level.” Even if a beneficiary were to request a formulary exception, what beneficiaries were not to be told is that CVS had put into place a “block” where these requests would be automatically denied. Moreover, even with the higher percentage coinsurance for the generic exception, due to the dramatic difference in drug pricing the generic ledipasvir/sofosbuvir 90MG-400MG tablets will always be less expensive.

516. If asked whether “HARVONI TABLETS [will] cost more than ledipasvir/sofosbuvir 90MG-400 MG tablets in any stage of the Medicare D benefit for non-LIS beneficiaries,” SilverScript CCRs were to tell beneficiaries “[t]his will vary based on your Plan and which Medicare Part D coverage stage you currently are in (*e.g.*, Deductible, Initial Coverage Limits, Coverage Gap or Catastrophic).”³³³ This was deceptive and false. SilverScript CCRs were trained to not to provide generic subsidy members costs in comparison to the cost of the brand-name Harvoni, leaving beneficiaries without information to determine actual cost differences. If they were being truthful, here is what CCR’s should have told LIS beneficiaries:

- The cost to LIS 1 beneficiaries in the initial coverage stage for CY2019 is \$8.50 for the brand and \$3.40 for the generic ledipasvir/sofosbuvir 90MG-400MG tablets.
- Beneficiaries will pay \$0 for both the brand and the generic ledipasvir/sofosbuvir 90MG-400MG tablets in the Catastrophic Coverage stage.
- Medicare Part D will pay \$10,661.89 for the brand (\$10,670.39- \$8.50) and \$4,973.88 for the generic ledipasvir/sofosbuvir 90MG-400MG tablets (\$4,977.28 - \$3.40) in the ICL stage.
- Medicare Part D will pay \$8,075.13 for the brand (\$8,083.63 - \$8.50) and \$4,600.58

³³³ *Id.*

for the generic ledipasvir/sofosbuvir 90MG-400MG tablets (\$4,603.98 - \$3.40) in the Coverage Gap (where applicable).

- Medicare Part D will pay \$1,616.73 for the brand and \$622.16 for the generic ledipasvir/sofosbuvir 90MG-400MG tablets in the Catastrophic Coverage stage (full amount of beneficiary's cost) in addition to 80% of the cost of either drug for the Medicare portion of the cost of the drugs in this stage.

517. If SilverScript CCRs were asked “[w]hy is the brand-name HARVONI TABLETS on the formulary when there is now a generic available,” they were trained to say:

In this case, the price of the generic version of HARVONI TABLETS will likely be similar to the price of the brand version for a minimum of six months, and perhaps longer. There are few manufacturers of the generic version of HARVONI TABLETS to drive the price down. Until there are competitors and the price of the generic version goes down, your plan will continue to cover brand-name HARVONI TABLETS at the Specialty Tier (Tier 5) cost share in 2019.³³⁴

The CCR statement about how long it will take for the price of generic ledipasvir/sofosbuvir 90MG-400MG tablets to come down was false. The generic ledipasvir/sofosbuvir 90MG-400MG tablets was, in fact, already much lower in price for most beneficiaries. There was no need to wait for there to be multiple generic manufacturers to drive the price down.

518. If SilverScript CCRs were asked by a beneficiary “[w]hy can’t I get the generic? Aren’t generics less expensive,” they were directed to say:

When a generic version is first available, it is typically similar in price to the brand version. At this time the generic version, called ledipasvir/sofosbuvir 90MG-400MG tablets, is not on the formulary. You do have the option to request a formulary exception. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.³³⁵

³³⁴ *Id.*

³³⁵ *Id.*

The CCR statement about generic pricing was misleading. While this statement may have been true for some newly released generics, the generic ledipasvir/sofosbuvir 90MG-400 MG tablets was a much lower cost option for all beneficiaries. It was also deceptive because it was intended to discourage beneficiaries from asking for a formulary exception by deceiving them. A formulary exception for the generic ledipasvir/sofosbuvir 90MG-400 MG tablets would have been approved at the highest tier (Tier 4) with a coinsurance of 40%. However, even with the higher coinsurance, the generic is much less expensive than the brand due to the dramatic difference in price.

519. If SilverScript CCRs were asked by beneficiaries “[h]ow long will HARVONI TABLETS remain on the formulary on the Specialty Tier (Tier 5),” they were trained to respond: “We anticipate that HARVONI TABLETS will remain on the formulary on the Specialty Tier (Tier 5) in 2019 until the price of the generic form of HARVONI TABLETS drops. We anticipate it will be a minimum of six months, however that is based on market conditions not within our control and could change.”³³⁶

520. The CCR statement about generic pricing was misleading. By February 2019, the GoodRx price of the generic ledipasvir/sofosbuvir 90MG-400 MG tablets was \$12,117.14 compared to the brand Harvoni price of \$32,127.27, already making the generic a lower cost option for both the beneficiary and Medicare Part D.

521. Thus, the decision to keep brand-name Harvoni as the only choice on the SilverScript formulary was not driven by market conditions, but CVS Health profit. Likewise, it was a lie and deceptive to say that the market conditions were not “within our control” when it was CVS Caremark’s agreement with Gilead that was the cause for the delay in the formulary

³³⁶ *Id.*

access to the less costly generic drug ledipasvir/sofosbuvir 90MG-400 MG tablets. The market conditions were thus completely within its control.

522. If SilverScript CCRs were asked by a beneficiary if they could request a coverage determination for the less costly generic, they were to respond: “Yes, you as the beneficiary may request a coverage determination for ledipasvir/sofosbuvir 90MG-400 MG tablets. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.”³³⁷ This was misleading. It was intended to discourage beneficiaries from asking for a formulary exception. A formulary exception for the generic would have been approved at the highest tier (Tier 4) with a coinsurance of 40%. However, even with the higher coinsurance, the generic is still much less expensive than the brand-name Harvoni due to the dramatic difference in price. This is also deceptive. What beneficiaries are not to be told is that, in the case of Harvoni, CVS has taken the extra step to automatically deny any formulary exception requests.

3. Beneficiary No. 5

523. When CVS Health realized how much more profit could be made if higher-priced drugs were *only* filled instead of less costly identical authorized generic versions, CVS Health went beyond just withholding of information about the right to seek a formulary exception and began making outright denials of all formulary exceptions and appeals for certain of the SSG/DNS Drugs, including Gilead’s expensive drugs Harvoni and Epclusa.

524. The misleading and false information often had a chilling effect on beneficiaries filling their prescriptions for potentially life-saving drugs.

525. One such instance that Relator remembers distinctly involved a seriously ill

³³⁷ *Id.*

member from Nebraska. A nurse caring for Beneficiary No. 5 called requesting the less costly generic version of Epclusa, sofosbuvir/velpatasvir 400MG-100MG tablets. The nurse made numerous calls on behalf of Beneficiary No. 5, doing everything she could to get the member the generic for completion of therapy because, as she indicated in the calls, the member would not be able to afford to continue therapy with the much more expensive brand drug Epclusa.

526. As Relator heard on recorded CCR calls, the nurse was continually lied to and blocked from getting the less costly, generic Epclusa despite the nurse's best efforts. On information and belief, because he never was given the option to request a coverage determination for the less costly sofosbuvir/velpatasvir 400MG-100MG tablets, Beneficiary No. 5 interrupted his Epclusa therapy because he could not afford it.

527. As part of its assessment of whether the Harvoni/Epclusa SSG fraudulent scheme would be detected, the CVS Health Executive Committee considered that the risk would be low because of its forecast that, of the 1604 Harvoni/Epclusa SilverScript prescriptions it projected per month, some 84% of the impacted SilverScript beneficiaries were on LIS subsidy and thus any higher copayments resulting from the Scheme would be absorbed by Medicare.

528. As such, because these LIS members would not be seeing the much higher copays at the point of sale, they were less likely to be concerned about the drastic differences in SSG Drug pricing being passed on to Medicare Part D.

529. So, even if the difference in price between the generic and the brand-name drug would often be many thousands of dollars, for an LIS beneficiary the out-of-pocket cost would be essentially the same. With the out-of-pocket cost thus minimally affected, the Executive Committee determined the SSG/DNS Scheme was a "low risk" of detection because these SilverScript beneficiaries (the majority of whom are LIS members) had much less incentive to file

complaints or grievances to get a less costly generic drug.

530. CVS Health has thus required its subsidiary SilverScript resort not only to misleading, but in outright lying to beneficiaries and having its CVS Pharmacies intentionally not stocking the generic medications on their shelves. For CVS Health to coordinate with its subsidiaries to mislead, lie, and otherwise deceive beneficiaries violated its fundamental obligations under the FTC Consent Order that it would not, directly or indirectly, make deceptive claims about the price or cost of Medicare Part D prescription drugs as well as its obligation of good faith and fair dealing in all its dealings with Medicare and Part D beneficiaries. Nothing in the law countenances such conduct.

4. Beneficiary No. 6

531. Another way CVS Health accomplished its goal of preventing beneficiaries from getting the less costly generic was having its subsidiary SilverScript provide misleading information about the true cost of the drugs, implying that the generic would be more expensive when it was not, thus intentionally deceiving beneficiaries about whether they should seek formulary exceptions.

532. On February 4, 2019, Beneficiary No. 6 (a 67-year-old man from New Mexico) attempted to fill a prescription for sofosbuvir-velpatasvir (authorized generic for brand-name Epclusa) at his pharmacy. The allowed cost for the drug was \$8,083.20 with a total cost to Medicare for the authorized generic fill estimated to be \$734.09. But, the order was reversed and not filled, apparently because Beneficiary No. 6 was concerned about the cost of the drug.³³⁸

533. On February 11, 2019, Beneficiary No. 6 attempted to fill a prescription for brand-name Epclusa. The allowed cost for the drug was \$25,179.17 with a total cost to Medicare for the

³³⁸ Exhibit 36 (CVS-002294).

brand-name fill estimated to be \$13,865.12. But, the order was reversed and not filled, again apparently because he was concerned about the cost of the drug.

534. On the same day, Beneficiary No. 6 and his spouse placed a call to CVS Health Customer Care to ask what happened. Beneficiary No. 6 and his wife wanted to “get a price” for the drug so they could “know how much it’s going to cost, if we can afford it.”³³⁹

535. On the call, the SilverScript CCRs gave incorrect information to prevent Beneficiary No. 6 from getting the authorized generic sofosbuvir-velpatasvir. Beneficiary No. 6 was incorrectly told that Epclusa was at the time a Tier 4 drug (it was at the time a Tier 5 drug).³⁴⁰

536. Beneficiary No. 6 was eventually transferred to a different CCR to discuss alternatives. The representative did not inform Beneficiary No. 6 that there was a less costly authorized generic alternative to her Epclusa prescription.

537. Beneficiary No. 6 was transferred yet again to another CCR. This time the representative misled Beneficiary No. 6 about the true cost of filling the brand-name versus the authorized generic by only giving the price for the first fill of the sofosbuvir-velpatasvir and the brand-name Epclusa. While the cost would be similar for the first fill (only approximately a \$400 difference), the costs for subsequent fills would be very different given that the Beneficiary No. 6 would be pushed into the Catastrophic Coverage stage of the Part D benefit where he would be responsible for 5% of either drug. This was especially misleading because Beneficiary No. 6 called inquiring about an 84-day supply of the drug – a total of three 28-day fills.³⁴¹

³³⁹ Exhibit 37 (CVS-001608).

³⁴⁰ *Id.*

³⁴¹ *Id.*

538. The situation involving Beneficiary No. 6 demonstrates how not informing patients about less costly generic options to the SSG/DNS Drugs and their right to request a coverage determination for the formulary exceptions has resulted in many thousands of SilverScript beneficiaries being forced to choose the much more expensive brand-name drug instead of less costly, equivalent (identical) alternative (and therefore affordable) generic.

539. It also underscores yet again how CVS Health violated its obligations in the FTC Consent Order that it would not, directly or indirectly, make deceptive claims about the price or cost of Medicare Part D prescription drugs as well as its obligation of good faith and fair dealing in all its dealings with Medicare and Part D beneficiaries.

5. *Beneficiary No. 7*

540. Beneficiary No. 7's story illustrates how CVS Health's subsidiary SilverScript began to outright deny all requests for less costly versions of brand-name medication, regardless of merit. It also highlights how the SSG/DNS Scheme is particularly egregious for LIS beneficiaries who are in need of high-priced, life-saving drugs. With high-priced drugs for LIS beneficiaries, Medicare is subsidizing most of the cost and the LIS beneficiaries often pay relatively small co-pay amounts making them less likely to complain about the higher-priced brand-name drugs. For those beneficiaries who do still try to get the authorized generic version, however, they are thwarted by CVS Health as a matter of company policy.

541. Beneficiary No. 7 (a 66-year-old man from Arkansas) was a SilverScript beneficiary receiving the low-income subsidy. He got a prescription for Epclusa to treat his hepatitis C, and filled it with brand-name Epclusa on November 5, 2018 at his pharmacy. The total cost to Medicare for the brand-name medication was \$20,872.59. As an LIS beneficiary, his cost was subsidized by Medicare during both the initial coverage and coverage gap (where applicable) for a total of \$5,364.29 in addition to covering the cost of the drug in the catastrophic coverage

stage (\$15,335.87). Beneficiary No. 7 paid a copay of \$8.35.³⁴²

542. Even though his copayment was relatively low in comparison with the overall cost of Harvoni, on January 10, 2019 Beneficiary No. 7 nevertheless requested a formulary exception to get Sofosbuvir-Velpatasvir (authorized generic Epclusa). But, pursuant to the fraudulent scheme, the very same day SilverScript automatically denied the formulary exception request using language specifically developed for the Epclusa authorized generics.

543. The formulary exception denial letter dated January 11, 2019 that was sent to Beneficiary No. 7 had been specifically modified from the SilverScript standard language to include the new blanket denial of formulary exceptions implemented for Epclusa authorized generics. It included language denying a formulary exception to Beneficiary No. 7 unlike any language SilverScript had ever used for any SSG/DNS Drug before, stating it denied the exception for the generic version of Harvoni (ledipasvir/sofosbuvir) – *i.e.*, the fact that they are authorized generic to Harvoni. The newly modified “same effectiveness” language in the denial letter reads:

Both the brand Harvoni and generic version of this drug, Ledipasvir/sofosbuvir, **would be expected to have the same effectiveness in treating your condition. The brand drug on the formulary and its generic contain the same active medications. They both contain the same inactive ingredients such as dyes, and would be expected to have the same risk of causing adverse effects (side effects).** Talk to your prescriber to see if any of the formulary alternative(s) would be right for you.³⁴³

544. The letter was configured only as an attempt to meet CMS requirements so as not to draw attention in an audit. There are psychological factors to consider as well. All generics have the same active ingredient and all would have the same effectiveness. But, if the beneficiary

³⁴² Exhibit 38 (CVS-002272).

³⁴³ Exhibit 39 (CVS-002280). (emphasis added).

does not initiate therapy because he cannot afford the drug, the denial would ignore altogether the “Social Determinants of Health” (also called “SDoH”).³⁴⁴

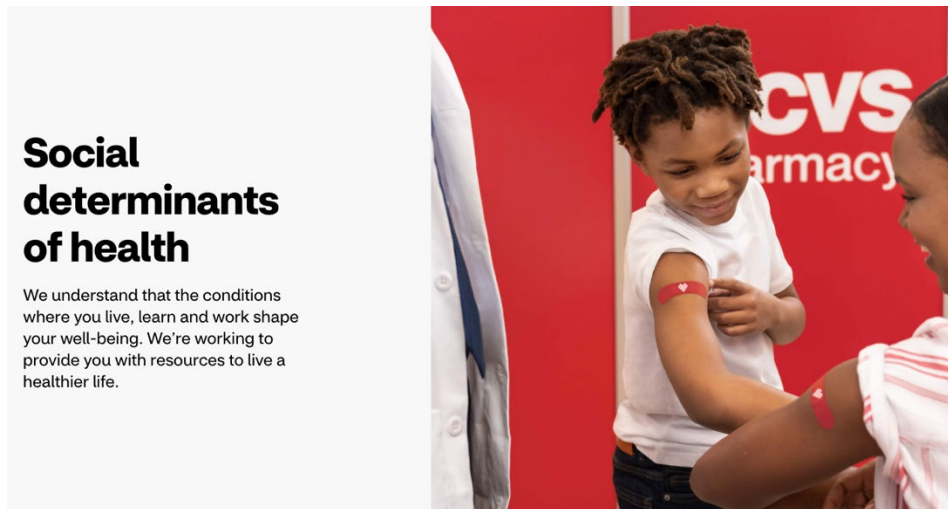
545. While SDoH can impact people from across the economic spectrum, low-income individuals are particularly likely to face challenges related to housing, food, and transportation. LIS beneficiaries are low-income by definition and would be key target populations for addressing social needs. There is strong evidence pointing to SDoH interventions as being cost effective, improving health outcomes.

546. CVS Health claims it supports use of SDoH. As a public relations effort to conceal its conduct, CVS Health has announced initiatives targeting SDoH.³⁴⁵ Here is an advertisement showing a young, smiling boy who has a CVS bandage on his arm, alongside the CVS Health claim that it is “working to provide you with resources to live a healthier life”³⁴⁶:

³⁴⁴ See Josh Lee, Melissa Majerol, Jeff Burke, *Addressing the social determinants of health for Medicare and Medicaid enrollees Leading strategies for health plans*, Deloitte Insights; *Innovative Approaches to Addressing Social Determinants of Health for Medicare Advantage Beneficiaries*, Better Medicare Alliance (Aug. 2021); Tany Feke, *How Medicare Addresses Social Determinants of Health Economics, Education, Health Care, Location, and Social Supports*, verywell health (Oct. 25, 2020).

³⁴⁵ See, e.g., Paige Minemyer, *CVS announces new initiatives targeting the social determinants of health*, Fierce Healthcare (July 24, 2019), available at <https://www.fiercehealthcare.com/payer/cvs-announces-new-initiatives-targeted-social-determinants-health>.

³⁴⁶ CVS Health, Social Determinants of Health, available at <https://www.cvshealth.com/health-with-heart/building-healthy-communities/social-determinants-of-health>.



547. This was just lip service. While CVS Health touts its support of SDoH initiatives, its SSG/DNS Scheme did exactly the opposite, making less costly authorized generic versions of wildly expensive drugs like Harvoni unavailable for thousands of SilverScript benefit who could not afford it.

548. What the SilverScript letter failed to tell Beneficiary No. 7 was that the brand Harvoni and the generic are the identical drug. Instead of telling Beneficiary No. 7 that they were in fact the same drug, the letter utilizes the clinical equivalency of the authorized generic ledipasvir/ sofosbuvir and brand-name Harvoni to obfuscate that there would be no legitimate reason to allow the formulary exception to obtain the less costly authorized generic version of the drug. The SilverScript letter to Beneficiary No. 7 concealed the real (and shadier) reason why the formulary exception would not be granted – the less costly price for Ledipasvir/sofosbuvir meant that CVS Health would not make as much money.

549. Beneficiary No. 7 then on January 14, 2019 attempted to obtain the generic sofosbuvir-velpatasvir (authorized generic for brand-name Epclusa) at the Hot Springs, Arkansas Smith Drug. The total cost to Medicare for the generic would have been \$6,871.15. However, the

claim was later reversed, indicating that the beneficiary never received the medication.³⁴⁷

550. The reversed claim was recorded in the CVS Health claim system, though, so the costs of the authorized generic versus the fill Beneficiary No. 7 have received on November 5, 2018 for Epclusa can be compared. The cost difference is dramatic:

	Generic (sofosbuvir-velpatasvir)	Brand (Epclusa)
Plan allowed drug cost	\$8,083.20	\$25,253.93
Member Co-pay	\$0	\$8.35
Plan Cost (SilverScript Cost)	\$1,212.55	\$4,373.49
Medicare Cost (Initial Coverage + Coverage Gap Stage)	\$404.18	\$5,508.30
Medicare Cost (Catastrophic Coverage Stage)	\$6,466.97	\$15,364.29
Total Medicare Cost	\$6,871.15	\$20,872.59

551. The SSG/DNS blocking strategy worked, however. Still needing this lifesaving medication despite being denied access to the identical drug (albeit the authorized generic), Beneficiary No. 7 filled the brand-name Epclusa medication three times: on January 21, 2019 at a cost to Medicare of \$19,988.92; on February 18, 2019 at a cost to Medicare of \$21,402.72; and in March at a cost to Medicare of \$21,402.72. Every fill for the brand-name Epclusa came at a much greater cost to Medicare.³⁴⁸

552. Not only that, but all the prescriptions for Beneficiary No. 7 were coded as “0 – NO DAW.” CVS Caremark’s Administrative Manual instructs pharmacists to “*Use the DAW 0 code when dispensing a generic drug*; that is, when no party (*i.e.*, neither Prescribing Provider, nor pharmacist, nor Participant) requests the branded version of a multi-source product.” (emphasis

³⁴⁷ Exhibit 40 (CVS-002287).

³⁴⁸ Exhibit 41 (CVS-002273); Exhibit 42 (CVS-002274); Exhibit 43 (CVS-002275).

added).³⁴⁹

553. CVS Caremark’s Provider Manual also includes a Reject Code for using a DAW Code 0 when dispensing a brand drug with available generics: “DAW 0 cannot be submitted on a multi-source drug with available generics. 407-D7, 408-D8.”³⁵⁰

554. Thus, a DAW 0 code in the PDE record in support of the SilverScript payment for Beneficiary No. 7 was untruthful, inaccurate and incomplete.

6. *Beneficiary No. 8*

555. Another SilverScript beneficiary’s story illustrates how the CVS Health scheme ensured only brand-name medications were dispensed despite a beneficiary’s considerable efforts to get less costly generics. SilverScript repeatedly blocked Beneficiary No. 8’s efforts to fill her prescription for the less costly authorized generic (ledipasvir-sofosbuvir). Ultimately, Beneficiary No. 8 would give up because SilverScript forced her to fill the prescription with the more expensive brand-name medication.

556. Starting in early February 2019, Beneficiary No. 8 (a 77-year-old woman living in New Jersey) made multiple attempts to fill ledipasvir-sofosbuvir at her pharmacy, but was rebuffed each time by SilverScript. The first instance SilverScript denied Beneficiary No. 8 access to the authorized generic version was in early February 2019 when WestRiver would not fill Beneficiary No. 8’s prescription for the authorized generic ledipasvir-sofosbuvir despite her submitting multiple requests.³⁵¹

³⁴⁹ Exhibit 1 (CVS-002944).

³⁵⁰ See CVS, “Reject Codes: Provider Manual Appendix B,” at p. 33 (June 1, 2019), <https://www.caremark.com/portal/asset/CVSCaremarkPayerSheetRejectCodes.pdf>

³⁵¹ Exhibit 44 (CVS-002175).

557. Given that her attempts to fill the authorized generic were denied, Beneficiary No. 8 contacted SilverScript and got a prior authorization for the brand-name medication, Harvoni, on February 11, 2019.

558. Yet, despite getting a prescription for the brand-name drug, Beneficiary No. 8 did not give up on trying to get the less costly authorized generic option. On February 12, 2019, Beneficiary No. 8 requested a formulary exception in order to get the authorized generic.³⁵²

559. Normally, SilverScript approved such exceptions with appropriate information from the prescriber. Until CVS Caremark entered into the Gilead deal, SilverScript had always granted formulary exceptions allowing beneficiary access to less costly generics. In this case, however, the exception was denied using the new SilverScript blanket denial that the authorized generic was not covered, with the new excuse that the brand-name drug and the generic were clinically equivalent drugs (ledipasvir-sofosbuvir and Harvoni).³⁵³

560. Beneficiary No. 8's additional attempts to fill her prescription with the authorized generic version were again denied at the pharmacy.

561. Nearly two weeks after initially trying to fill her first prescription (during which time she had delayed initiating her hepatitis C treatment), on February 19, 2019, Beneficiary No. 8 received a prior authorization for brand-name Epclusa, the brand-name version of sofosbuvir-velpatasvir, which is a similar drug as Harvoni and also would help cure Beneficiary No. 8's Hepatitis C. That same day, Beneficiary No. 8 finally relented and filled her prescription for the

³⁵² *Id.*

³⁵³ Exhibit 45 (CVS-002210).

brand-name Epclusa at a total cost to Medicare of \$19,952.86.³⁵⁴

562. Beneficiary No. 8 later attempted to refill her prescription on March 19, 2019 at her pharmacy, and requested the generic Epclusa, sofosbuvir-velpatasvir. This time, only because of a flaw in the claims logic (which was later eliminated), Beneficiary No. 8 was able to get the authorized generic version because of a Transition Fill. The authorized generic sofosbuvir-velpatasvir fill was at a cost of only \$6,854.74.³⁵⁵

563. Beneficiary No. 8's fills for the authorized generic and the brand-name Epclusa show just how large the price differences were:³⁵⁶

	Generic (sofosbuvir-velpatasvir)	Brand (Epclusa)
Plan allowed drug cost	\$8,064.00	\$25,119.76
Member Co-pay	\$0	\$3.80
Plan Cost (SilverScript Cost)	\$1,209.66	\$5,163.10
Medicare Cost (Initial Coverage + Coverage Gap Stage)	\$403.22	\$5,935.66
Medicare Cost (Catastrophic Coverage Stage)	\$6,451.52	\$14,017.20
Total Medicare Cost	\$6,854.74	\$19,952.86

564. After the fill for the authorized generic, Beneficiary No. 8 received a letter from SilverScript dated March 20, 2019 advising her that, although she had been able to receive a temporary one-time Transition Fill for sofosbuvir-velpatasvir, the generic drug is not covered on the formulary and would not be covered in the future.³⁵⁷ The letter did not mention that the generic

³⁵⁴ Exhibit 46 (CVS-002181).

³⁵⁵ Exhibit 47 (CVS-002230).

³⁵⁶ Exhibits 46 & 47.

³⁵⁷ Exhibit 48 (CVS-002235).

sofosbuvir-velpatasvir is identical to the much more expensive brand-name Epclusa.

565. On April 15, 2019, Beneficiary No. 8 again attempted to fill her prescription for the generic sofosbuvir-velpatasvir, but it was denied again because there was no formulary exception approval. That same day, Beneficiary No. 8's request for a formulary exception for the authorized generic sofosbuvir-velpatasvir was also denied. Beneficiary No. 8 submitted a formulary exception redetermination the next day on April 16, 2019 and was denied yet again with language indicating that the same "effectiveness in treating your condition" would be expected.³⁵⁸ This is new language that was crafted specifically for the CVS Caremark deal with Gilead to block the authorized generics ledipasvir-sofosbuvir and sofosbuvir-velpatasvir. Illustrating the scope of CVS Health's deception, no other SSG/DNS formulary exception approvals had ever before been held to the same standard by SilverScript. In every other instance prior to this, SilverScript had granted the SSG/DNS formulary exception.

566. On April 18, 2019, Beneficiary No. 8 tried one last time to get sofosbuvir-velpatasvir filled and was denied once more. However, after days of obfuscation by CVS Health aimed at wearing down her determination to get the less costly drug, the same day she finally surrendered and got a prescription for brand-name Epclusa. The total cost for the fill of Epclusa is \$21,351.80.³⁵⁹

567. Beneficiary No. 8's experience demonstrates SilverScript's repeated blocking of the less costly authorized generic versions of both Epclusa and Harvoni. The blocking happened despite the numerous requests from the beneficiary to have the authorized generic covered through

³⁵⁸ Exhibit 49 (CVS-002224).

³⁵⁹ Exhibit 50 (CVS-002180).

a formulary exception. She was never told by SilverScript that the brand-name Harvoni and Epclusa were in fact identical to the less costly authorized generic.

568. Beneficiary No. 8's story again clearly illustrates the substantial difference in cost covered by Medicare for the brand-name version of the drug (\$19,952.86) and the authorized generic version (\$6,854.74). Even if the manufacturer of Epclusa (Gilead) had paid substantial rebates on the list price, Medicare is still picking up a higher cost versus the authorized generic version for a beneficiary like Beneficiary No. 8 given the price of the drug and her LIS status. For the February fill, Medicare paid the higher LIS amount regardless of any rebates.

569. The claim record shows that the pharmacy filled Beneficiary No. 8's Epclusa prescriptions and submitted the claim with DAW Code 0.³⁶⁰

570. CVS Caremark's Administrative Manual instructs pharmacists to "*Use the DAW 0 code when dispensing a generic drug*; that is, when no party (*i.e.*, neither Prescribing Provider, nor pharmacist, nor Participant) requests the branded version of a multi-source product." (emphasis added).³⁶¹

571. CVS's Provider Manual also includes a Reject Code for using a DAW Code 0 when dispensing a brand drug with available generics: "DAW 0 cannot be submitted on a multi-source drug with available generics. 407-D7, 408-D8."³⁶²

572. Thus, a DAW 0 code in the PDE record in support of the SilverScript payment for Beneficiary No. 8 was untruthful, inaccurate and incomplete.

³⁶⁰ *Id.*

³⁶¹ Exhibit 1 (CVS-002944).

³⁶² See CVS, "Reject Codes: Provider Manual Appendix B," at p. 33 (June 1, 2019), <https://www.caremark.com/portal/asset/CVSCaremarkPayerSheetRejectCodes.pdf>.

573. In addition to rebuffing Beneficiary No. 8's numerous attempts to get the less costly authorized generic, Beneficiary No. 8's Epclusa prescription was filled in violation of New York State law requiring generic substitution, causing false claims to be submitted because the unsubstituted claims are invalid prescriptions under State law and thus not eligible for reimbursement by the SilverScript.

574. This illustrates graphically that, by not allowing substitution of the less costly generic authorized version of the Beneficiary No. 8's prescription, CVS Health and its subsidiary SilverScript had violated the terms of the Consent Order that it would not, directly or indirectly, make deceptive claims about the price or cost of Medicare Part D prescription drugs.

7. *Beneficiary No. 9*

575. Beneficiary No. 9's story demonstrates how SilverScript's policy of denying all formulary exceptions for Epclusa drove beneficiaries into the Catastrophic Coverage stage after only one fill of the drug. Like the other beneficiaries who tried to obtain formulary exceptions in order to get less costly versions of Harvoni or Epclusa, Beneficiary No. 9's request was summarily denied.

576. On January 14, 2019, Beneficiary No. 9 (an 83-year-old woman from California) attempted to fill a prescription for sofosbuvir-velpatasvir (authorized generic for brand-name Epclusa), but the claim was rejected because Beneficiary No. 9 did not have a formulary exception.³⁶³

577. The same day, Beneficiary No. 9 requested a formulary exception, but the request was denied the following day, using the new SilverScript blanket denial letter.³⁶⁴

³⁶³ Exhibit 51 (CVS-002262).

³⁶⁴ Exhibit 52 (CVS-002264).

578. As a result of the formulary exception denial, Beneficiary No. 9 had no option but to fill her prescription for the brand-name drug, Epclusa, at her pharmacy.

579. For fills of Epclusa in January and February, the cost for the brand-name Epclusa to Medicare was \$20,459.82 and \$21,351.80 respectively – over three times higher cost than it would have been for the authorized generic version.³⁶⁵

580. According to Beneficiary No. 9's January 31, 2019 Explanation of Benefits,³⁶⁶ together with the other medications she was receiving (Irbesartan tab 300 mg, Olapatadine SOL 0.2%, Xiidra drops 55, Fluticasone SPR 50 mcg, and Levocetirizi tab 5 mg), she was pushed into the Catastrophic Coverage stage after only one fill of Epclusa in January. However, because her yearly income and resources were below certain limits, she was entitled to "Extra Help" as an LIS beneficiary, meaning that the high cost of Epclusa alone would end up making Medicare would subsidize all her drugs earlier than if the generic had been dispensed throughout the rest of 2019.

8. Beneficiary No. 10

581. The story of Beneficiary No. 10, a 63-year-old woman from Oregon, illustrates how beneficiaries have attempted to receive the less costly authorized generic version of Harvoni, only to be repeatedly turned down by SilverScript.

582. Beneficiary No. 10 first filled a prescription for Harvoni on January 14, 2019 at her pharmacy. The plan allowed cost for Harvoni was \$32,198.04, of which her LIS copay was \$3.80 and the Medicare cost was between \$29,000 and \$30,000.

583. On February 5, 2019, Beneficiary No. 10 successfully received a prescription for the generic ledipasvir-sofosbuvir due to a flaw in the Transition Fill logic (which was later

³⁶⁵ Exhibit 53 (CVS-002242) and Exhibit 54 (CVS-002243).

³⁶⁶ Exhibit 55 (CVS-002254).

eliminated). The plan allowed cost was \$12,265.92, the member copay was \$0, and the total Medicare cost was \$10,426.46.³⁶⁷

584. Soon after the fill for the authorized generic, Beneficiary No. 10 received a letter from SilverScript dated February 7, 2019, advising her that, although she had been able to receive a temporary one-time Transition Fill for ledipasvir-sofosbuvir, the generic drug was not covered on the formulary and would not be covered in the future.³⁶⁸ The letter did not mention that the ledipasvir-sofosbuvir is a less costly authorized generic to the brand-name Harvoni. While the letter tells her that she has the right to request a coverage determination, including a formulary exception to receive the generic, it does not tell her that because of the clandestine deal CVS Caremark had struck with Gilead, the right to a formulary exception was illusory and it would be summarily denied by SilverScript.

585. The result for Beneficiary No. 10 was that the SilverScript deception had denied her request to receive the less costly (and identical) generic, increasing not only her copayment, but the Medicare cost by over \$20,000 per prescription.

9. Beneficiary No. 11

586. The story of Beneficiary No. 11 illustrates how CVS Health's gamesmanship resulted in a patient being repeatedly blocked from receiving access to necessary care. Ultimately, it appears that Beneficiary No. 11 may never have completed treatment for his Hepatitis C, an illness that can cause serious health problems, including liver damage, cirrhosis (scarring of the liver), liver cancer, and even death.

587. On March 6, 2019 and again on March 11, 2019, Beneficiary No. 11 (a 38-year-old

³⁶⁷ Exhibit 56 (CVS-002166).

³⁶⁸ Exhibit 57 (CVS-002169).

male from Maryland) attempted to fill a prescription for generic Harvoni (ledipasvir-sofosbuvir), at his pharmacy. The prescription was reversed (*i.e.*, never completed) three times by CVS Health, suggesting that Beneficiary No. 11 was looking for lower cost options than Harvoni.

588. On March 14, 2019, Beneficiary No. 11 called SilverScript, complaining that he “cannot afford” the more expensive brand-name Harvoni prescription, and requested a price reduction. SilverScript at first treated his request as a grievance and transferred his call to Coverage Exception Review (“CER”) for a tiering exception to receive the less costly generic, but the exception was denied according to the new SilverScript standard for blocking all such requests for Harvoni and Epclusa. As he had been trained, at no time did the CER representative advise Beneficiary No. 11 there were alternatives that are not on the formulary, including the less costly authorized generic ledipasvir-sofosbuvir.³⁶⁹

589. Later that same day, Beneficiary No. 11 called again seeking the less costly generic. Initially, the call was treated as a grievance, but this time he was transferred to Coverage Determinations & Appeals, where his request for a formulary exception to receive the less costly generic was denied. Consistent with CCR training, the representative failed to tell him that, even though he was seeking access to the identical formulation of the drug, no matter the merits of the formulary exception request for the generic ledipasvir-sofosbuvir, it would be summarily denied.

590. Thereafter, on that same day, Beneficiary No. 11 filled the prescription for Harvoni at his pharmacy with a member copay (subsidy level 1) of \$8.50, SilverScript cost of \$4,556.84, and total Medicare cost of \$27,633.20.

591. The claim record shows that his pharmacy filled Beneficiary No. 11’s Harvoni

³⁶⁹ Exhibit 58 (CVS-002887).

prescription and submitted the claim with DAW Code 0.³⁷⁰

592. CVS Caremark’s Administrative Manual instructs pharmacists to “*Use the DAW 0 code when dispensing a generic drug*; that is, when no party (*i.e.*, neither Prescribing Provider, nor pharmacist, nor Participant) requests the branded version of a multi-source product.” (emphasis added).³⁷¹

593. CVS’s Provider Manual also includes a Reject Code for using a DAW Code 0 when dispensing a brand drug with available generics: “DAW 0 cannot be submitted on a multi-source drug with available generics. 407-D7, 408-D8.”³⁷²

594. Thus, a DAW 0 code in the PDE record in support of the SilverScript payment for Beneficiary No. 11 was untruthful, inaccurate and incomplete.

595. On March 26, 2019, April 4, 2019, and April 5, 2019, Beneficiary No. 11 again attempted to fill Harvoni prescriptions at his pharmacy four different times, but none of the four claims was processed, suggesting he was still looking for lower cost options than Harvoni.

596. Most concerning is that, based on the claims record, there is no evidence that Beneficiary No. 11 ever received his second and third fills for either Harvoni or ledipasvir-sofosbuvir. Beneficiary No. 11 had made numerous attempts to receive the less costly generic, doing everything he possibly could to get the less costly generic for completion of his therapy, apparently because he could not afford Harvoni. Despite his best efforts, Beneficiary No. 11 was continually lied to and blocked from getting the less costly generic Harvoni.

597. On information and belief, because he never was given the option to request a

³⁷⁰ Exhibit 59 (CVS-002892).

³⁷¹ Exhibit 1 (CVS-002944).

³⁷² See CVS, “Reject Codes: Provider Manual Appendix B,” at p. 33 (June 1, 2019), <https://www.caremark.com/portal/asset/CVSCaremarkPayerSheetRejectCodes.pdf>.

coverage determination for the less costly (and identical) ledipasvir-sofosbuvir, Beneficiary No. 11 interrupted his Harvoni therapy because he could not afford it.

598. Furthermore, because the prescription was filled in Maryland, a mandatory generic substitution State, SilverScript violated the State law requirement that the prescription be substituted with a less costly generic.

10. CVS Health Repeatedly Rejected Beneficiaries' Attempts to Fill Generic Harvoni and Epclusa

599. Following the implementation of the SSG/DNS Scheme for Harvoni and Epclusa, CVS Health has routinely rejected thousands of beneficiary attempts to obtain access to less costly authorized generic of these drugs. Attached hereto as Exhibit 60 is a representative sampling of 148 denied SilverScript claims for the authorized generic Harvoni and Epclusa prescriptions for just the month of January 2019, shortly after the SSG/DNS Schemes began. The list includes 51 claims which were denied where the prescriptions for these drugs would have been filled in a mandatory substitution State.

600. Each of these beneficiaries was sent SilverScript's letter including the blanket denial of formulary exceptions implemented for Harvoni and Epclusa authorized generics. It included the new language denying a formulary exception unlike any language CVS Health had ever used before, stating it denied the exceptions for ledipasvir/sofosbuvir (authorized generic for brand-name Harvoni) or sofosbuvir/velpastasvir (authorized generic for brand-name Epclusa) based on their clinical equivalence – *i.e.*, the fact that they are authorized generics to Harvoni and Epclusa.

601. Never before had CVS Health used as an excuse with any other SSG/DNS Drug that the drugs were clinically equivalent as a basis to deny a formulary exception requested by any beneficiary requesting the less costly generic to a SSG/DNS brand-name drug.

602. For years, even when the preferred drug was in its SSG/DNS Program, SilverScript had universally allowed all formulary exceptions to dispense the less costly generic. For the first time, the rebate deal that CVS Caremark had inked with Gilead required that SilverScript would deny all formulary exceptions for generic versions of Harvoni and Epclusa.

603. The formulary exception letter sent to beneficiaries rejecting their requests for the less costly (and identical) generic ledipasvir/sofosbuvir or sofosbuvir/velpastavir is an explicit violation of the Consent Order that it would not, directly or indirectly, make deceptive claims about the price or cost of Medicare Part D prescription drugs.

604. The letter tells beneficiaries that they had the right to ask for an appeal of the denial of the formulary exception. What the letter from SilverScript failed to mention was that the result of any appeal was already predetermined – *i.e.*, CVS Caremark had already agreed with Gilead that SilverScript would deny all appeals.

605. What is even more sinister is that, while the language included in the SilverScript denial letters for Epclusa and Harvoni formulary exceptions appears to track the Medicare guidance on formulary exceptions, the guidance language it was modeled after appears to have been intended for the opposite situation – *i.e.*, a patient was requesting a formulary exception for a more expensive brand drug instead of a less costly on-formulary generic.

606. Illustrating how perverse its new-found insistence that clinical equivalence would become a sufficient reason to deny all formulary exceptions for Harvoni and Epclusa, for years SilverScript has used DAW 1 (physician requests brand) as a justification to switch from the identical authorized generic to the brand-name SSG Drug, even requiring physicians to request the brand in those instances when there was no medical reason for dispensing the brand instead of the identical generic.

607. However, under the NCPDP standards, DAW Code 1 may only be “used when the prescriber indicates, in a manner specified by prevailing law, *that the product is Medically Necessary* to be Dispensed As Written.” (emphasis added)³⁷³ Even though there was no medical necessity requiring use of the brand instead of the generic, there are tens of thousands of examples where SilverScript required the beneficiary seeking access to an authorized generic to switch to the preferred brand, coding the claim as DAW 1. The only reason for coding these “clinically equivalent” prescriptions as DAW 1 was the fact that the SSG/DNS Scheme was blocking the generic.

608. With the Harvoni and Epclusa denial letters, however, SilverScript has engaged in the pretense of using an ethically questionable, technical loophole to keep patients and Medicare paying for the more expensive brand-name drugs instead of using the less costly authorized generics. This is not only wholly contrary to the intent of the formulary exception criteria and the purpose of the Medicare guidance language, it is completely at odds with its own position about the “Social Determinants of Health” and its commitment to making less costly drugs available to ensure patient adherence and healthy outcomes.

609. The result of this charade not only deceived beneficiaries, it has resulted in significant increased profits to CVS Health while dumping huge additional costs for Harvoni and Epclusa onto taxpayers and Part D beneficiaries, thereby violating the FTC Consent Order that it would not, directly or indirectly, make deceptive claims about the price or cost of Medicare Part

³⁷³ CMS recognizes that “excessive use” of DAW Code 1 on multi-source products may raise “red flags from an audit perspective.” See Centers for Medicare and Medicaid Services, *Pharmacy Self-Auditing: Control Practices to Improve Medicaid Program Integrity and Quality Patient Care; Booklet 4: Billing Practices*, December 2015, available at: <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/pharmacy-selfaudit-booklet4-billing-practice.pdf>.

D prescription drugs.

610. HHS and CMS have expressly addressed the very concerns at issue in this case in its November 30, 2020 final rulemaking (the “Rebate Rule”), stating that “rebates also may create a perverse incentive that rewards manufacturers for increasing their list price, while subjecting consumers to higher out-of-pocket costs. Since beneficiary out-of-pocket costs are often calculated based on the list price of the drug (*i.e.*, before rebates are paid), beneficiaries pay higher cost-sharing than they would if discounts were reflected at the point of sale. Furthermore, high list prices may result in more beneficiaries more quickly reaching the catastrophic phase, where the Federal government bears 80 percent of the drug costs and the Part D plans only cover 15 percent of the drug costs.”³⁷⁴

611. In response to industry comments about the impact rebates have on increasing on Medicare Part D beneficiary costs, the HHS/CMS Rebate Rule cited the Gilead press release that the company would be introducing authorized generics of Harvoni and Epclusa because it could not “quickly” lower list prices for the brand-name drugs once already locked into a PBM rebate agreement.³⁷⁵ These are the same Gilead authorized generics that SilverScript was blocking in favor of the more expensive brand-name Harvoni and Epclusa.

612. The increased costs for Harvoni and Epclusa in relation to their authorized generics are also the subject of a soon-to-be-issued 2022 HHS OIG report, *How Part D Plans’ Preference*

³⁷⁴ See Final Rule, *Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals*, 85 Fed. Reg. 76666, 76667 (Nov. 30, 2020).

³⁷⁵ *Id.* at 76686, n.34 (citing *A perspective from our CEO: Gilead Subsidiary to Launch Authorized Generics to Treat HCV*, Gilead Pharmaceuticals (Sept. 24, 2018), <https://www.gilead.com/news-and-press/company-statements/authorized-generics-for-hcv>).

*for Higher Cost Hepatitis C Drugs Affects Medicare Beneficiaries.*³⁷⁶ The report summary states that Medicare Part D spent \$2.5 billion on hepatitis C drugs in 2019, some 93% of which was spent on three drugs, Harvoni, Epclusa and Mavyret. According to the summary, “[i]n early 2019, Gilead—the manufacturer of Harvoni and Epclusa—launched authorized generic versions of both drugs with the expressed goal of reducing patients’ out-of-pocket costs. The retail price of authorized generic versions is \$24,000, which is significantly less than the prices of Harvoni and Epclusa”³⁷⁷ According to CMS, “[t]hese lower list prices *should in turn lead to lower out-of-pocket costs, as authorized generics are as effective as branded versions but sell for only a fraction of the cost.* However, a preliminary analysis indicates that Medicare utilization has not shifted from brandname versions of Harvoni and Epclusa to their significantly less costly, authorized generic versions. . . .”³⁷⁸

F. Ventolin HFA

613. Albuterol sulfate inhalation aerosol is a short acting beta agonist or so-called “rescue inhaler” approved for the treatment or prevention of bronchospasm in patients aged 4 years and older with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm in patients aged 4 years and older.

614. Bronchospasms are the tightening and narrowing of the airways in the lungs causing difficulty in breathing. Asthma attacks can lead to death, but can be avoided with proper treatment and care. Access to affordable albuterol inhalers is a critical pharmacologic therapy

³⁷⁶ See HHS OIG, *How Part D Plans' Preference for Higher Cost Hepatitis C Drugs Affects Medicare Beneficiaries*, OIE-BL-21-00200, <https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000579.asp>.

³⁷⁷ *Id.*

³⁷⁸ *Id.* (emphasis added).

used to treat asthma symptoms and to ease breathing by opening airways during an asthma attack.

615. GSK manufactures albuterol sulfate inhalation aerosol under the brand-name Ventolin HFA.

1. CVS Health Entered into SSG/DNS Deal to Facilitate Evergreening of GSK's Ventolin HFA Product

616. Ventolin was first approved by the FDA in 1981, with a generic form approved in 1995. At the time it was approved, Ventolin used chlorofluorocarbons (CFCs) as a propellant. CFCs were banned by the FDA for use as a propellant in 2008 as ozone-depleting substances.³⁷⁹ GSK thereafter switched to the propellant hydrofluoroalkane (HFA). The FDA 2008 change all but eliminated generic competition for albuterol inhalers like Ventolin HFA, substantially increasing out-of-pocket costs for the drug, resulting in huge profits for GSK.³⁸⁰

617. GSK engaged in patent “evergreening” with Ventolin HFA, obtaining 15 secondary patents on the product delivery mechanism, artificially recycling and repurposing its Ventolin product with a new delivery mechanism to extend the product’s patent cliff.³⁸¹ GSK’s primary patent on Ventolin HFA eventually expired on February 24, 2019.

618. As part of its efforts to extend its exclusivity, on January 15, 2019, GSK announced

³⁷⁹ *Making the Switch: Prepare your patients for the phase-out of CFC-propelled albuterol inhalers*, FDA (Dec. 4, 2015), <https://www.fda.gov/drugs/resources-you-drugs/making-switch-prepare-your-patients-phase-out-cfc-propelled-albuterol-inhalers>.

³⁸⁰ Anupam Jena, Oliver Ho, Dana Goldman, *The Impact of the US Food and Drug Administration Chlorofluorocarbon Ban on Out-of-pocket Costs and Use of Albuterol Inhalers Among Individuals With Asthma*, 175 JAMA Intern Med. 1171-1179 (July 2015), <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2293081>.

³⁸¹ Reed Beall, Jason Nickerson, Warren Kaplan, Amir Attaran, *Is Patent “Evergreening” Restricting Access to Medicine/Device Combination Products?*, 11 PLOS One (Feb. 24, 2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4766186/>; Robin Feldman, *May your drug price be evergreen*, 5 Journal of Law and the Biosciences 590 (Dec. 7, 2018), <https://academic.oup.com/jlb/article/5/3/590/5232981>.

that Prasco would begin selling an authorized generic version of its Ventolin HFA (albuterol) inhalation aerosol. The authorized generic would be manufactured by GSK and sold by Prasco.³⁸² The only difference would be that there would be a different name on the label.

619. Prasco's authorized generic for Ventolin HFA had a wholesale acquisition cost (WAC) of \$36.00, representing a ~35% reduction in WAC cost compared to Ventolin HFA.

620. Prasco promotes itself as a leading manufacturer of authorized generics. It states that:

An Authorized Generic (AG) is the brand prescription product sold in private label packaging at generic prices. The AG is identical to the brand in every way; meaning that unlike standard generics, it contains the exact same active and inactive ingredients as the brand. And with the same shape, color, size, smell, taste and mouth feel, the AG provides a patient with the same overall experience as the brand product.

621. Publicly, CVS Health claims it is opposed to evergreening. On April 10, 2019, in written comments to questions from Representative Jeff Duncan (R-SC) before the House Oversight Committee, Thomas Moriarty, Executive VP, Chief Policy and External Affairs Officer, and General Counsel, had testified that: "[CVS Health] believes that patent evergreening is a problem generally in the pharmaceutical industry. For that reason we have recently endorsed a bill introduced by Senators Cornyn and Blumenthal, the Affordable Prescriptions for Patients Act, which would give FTC the authority to review pharmaceutical patenting practices."³⁸³

622. Executive VP Rice made similar comments before the Senate Finance Committee

³⁸² OptumRx, *Ventolin® HFA (albuterol) – First-time generic*, available at https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/new-generics/newgenerics_ventolinhfa_2019-0117.pdf.

³⁸³ Written comments of Thomas Moriarty, *Priced Out of Lifesaving Drugs: Getting Answers on the Rising Cost of Insulin*, Committee on Energy and Commerce Subcommittee on Oversight (April 10, 2019).

the day before, telling the Committee that Congress should prevent “evergreening,” which “would prevent brand manufacturers from artificially maintaining monopolies and lower costs long term.”³⁸⁴

623. Even though CVS Health claims it supports ending evergreening,³⁸⁵ arguing it had PBM “tools to lower drug prices,” privately it has entered into anticompetitive agreements with SSG/DNS Drug Makers which in actuality have enabled these practices to continue, blocking access to less costly generics in favor of more expensive brand-name drugs.

624. Ventolin HFA is one such example. Two months before Moriarty and Rice had testified to Congress that CVS Health opposed evergreening, CVS Caremark had entered into an agreement with GSK, requiring SilverScript add Ventolin HFA to the SSG/DNS Scheme effective February 7, 2019. Not only were prescription claims for the generic albuterol to be blocked by SilverScript, the Executive Committee decided on February 18, 2019 that the CVS Pharmacies would stop stocking the generic as well. This has meant not only that the authorized generic of Ventolin HFA was unavailable to SilverScript beneficiaries who filled scripts at the CVS Pharmacies, but also would not have been available to the 45 million Part D beneficiaries, many of whom would have filled their prescriptions at a CVS Pharmacy.

625. These blocking measures were highly controversial among the CVS Health leadership, with Relator and numerous others complaining that this could create serious access issues for patients needing the less costly generic version of the rescue inhaler Ventolin HFA.

³⁸⁴ Written comments of Derica Rice, Drug Pricing In America: A Prescription For Change, Part Iii, Committee On Finance United States Senate, S. Hrg. 116-415 (April 9, 2019).

³⁸⁵ *Lowering drug prices for consumers and clients*, CVS Health, <https://www.cvshealth.com/about-cvs-health/public-policy/lower-drug-prices-for-consumers-and-clients>; *Making Medications More Affordable*, CVS Health website.

There were concerns that blocking the generic would result in “[h]igher cost share for clients and members if they fill brand Ventolin” which would drive “questions/issues from clients.”³⁸⁶ If the “impact occurs on a weekend, members will be forced to go to another pharmacy or will be without a rescue inhaler until Dr can be reached” to write a new prescription.³⁸⁷

626. Not only that, but there were concerns that the collusion between SilverScript, CVS Caremark, and the CVS Pharmacies to block the generic Ventolin HFA could be an explicit violation of the firewall obligations with the FTC. For example, there were concerns that this would “cause noise” not just from SilverScript members, but from the rest of CVS Health’s Part D business managed by CVS Caremark because not only was the generic Ventolin HFA not being stocked in CVS mail and retail pharmacies,³⁸⁸ there were concerns with “associated sensitivity with CMS”³⁸⁹ and the “increased calls to Customer Care.”³⁹⁰

627. However, because of the richness of the rebate for the brand, CVS Health senior leadership on the Executive Committee decided it would not stock the Ventolin HFA generic in its pharmacies – essentially blocking the ability for many beneficiaries in the plan to have access to the less costly generic versions of this critical drug.

2. SilverScript Deception Blocked Access to the Less Costly Generic Ventolin HFA (albuterol sulfate HFA)

628. After Ventolin HFA was added to the SSG/DNS Scheme effective February 7, 2019, SilverScript CCRs were directed to tell beneficiaries:

³⁸⁶ Exhibit 65 (CVS-000020).

³⁸⁷ *Id.*

³⁸⁸ *Id.* (CVS-000015).

³⁸⁹ *Id.* at CVS-000016.

³⁹⁰ *Id.* at CVS-000018.

Generic prescription drugs are typically the lowest-cost option when compared to branded prescription drugs. SilverScript promotes the use of generic prescription drugs to help plan beneficiaries save money. During the initial launch phase for the generic, there will be few manufacturers marketing the generic and the cost of the generic is expected to be relatively high. To help keep out-of-pocket costs low, SilverScript is retaining brand VENTOLIN® HFA on its formulary on Preferred Brand Tier (Tier 3). VENTOLIN is eligible for a manufacturer discount in the coverage gap.³⁹¹

This is misleading. Authorized generics are eligible for the Coverage Gap discount program since they are NDA “applicable” drugs.³⁹² The statement about keeping out-of-pocket costs low is a lie. The generic drug option(s) are already lower cost to the member and Medicare than the brand Ventolin HFA in many cases.

629. SilverScript CCRs were also trained to say:

Retaining brand VENTOLIN HFA on Preferred Brand Tier (Tier 3) can help keep out-of-pocket costs low for SilverScript beneficiaries. Beneficiaries have the option to request an exception if they wish to obtain albuterol sulfate inhalation aerosol. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level. Brand VENTOLIN HFA is available at the Preferred Brand Tier (Tier 3) copay/coinsurance, so if the request for the generic is granted, the beneficiary would pay the amount associated with the plan’s exception tier. This may be a different cost than the brand.³⁹³

The statement about keeping out-of-pocket costs low was false. Keeping the brand would not have resulted in lower out-of-pocket costs for beneficiaries and Medicare Part D. The exception request statement intentionally is meant to discourage beneficiaries from asking for a formulary exception by using the language “highest cost share level.”

³⁹¹ Exhibit 61 (CVS-000294).

³⁹² CMS, *Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance* (May 21, 2010), at 4.

³⁹³ Exhibit 61 (CVS-000293-302).

630. When beneficiaries asked whether Ventolin HFA would cost more than albuterol sulfate inhalation aerosol in any stage of the Medicare D benefit, they were to tell subsidy members: “Maybe. In the Catastrophic Coverage Stage of the benefit, you will continue to receive VENTOLIN HFA at no cost. If you have not yet reached the Catastrophic Coverage Stage, you might have to pay your brand-name copayment for VENTOLIN HFA until you reach the Catastrophic Coverage Stage.”³⁹⁴ This was misleading because comparative costs are not provided, leaving beneficiaries without information to determine the actual impact. A truthful response would have been:

- The cost to LIS 1/LIS 2 beneficiaries in the initial coverage stage for CY2019 is \$8.50/\$3.80 for the brand and \$3.40/\$1.25 for the generic albuterol sulfate inhalation aerosol.
- Beneficiaries will pay \$0 for both the brand and the generic albuterol sulfate inhalation aerosol in the Catastrophic Coverage stage.
- In all scenarios for LIS 1 & 2 in 2019, the generic albuterol sulfate inhalation aerosol would have been less expensive for the beneficiary and Medicare.

631. When beneficiaries asked why brand-name VENTOLIN HFA is the only choice on the SilverScript formulary when there is now a generic albuterol sulfate inhalation aerosol available, SilverScript CCRs were to respond:

In this case, the price of the generic version of VENTOLIN HFA will likely be similar to the price of the brand version for a minimum of six months, and perhaps longer. There are few manufacturers of the generic version of VENTOLIN HFA to drive the price down. Until there are competitors and the price of the generic

³⁹⁴ *Id.*

version goes down, your plan will continue to cover brand-name VENTOLIN HFA at the Preferred Brand Tier (Tier 3) cost share in 2019.³⁹⁵

This is a lie. The generic albuterol sulfate inhalation aerosol was, in fact, already lower in price for most beneficiaries. There was no need to wait for there to be multiple generic manufacturers to drive the price down.

632. When beneficiaries asked why they cannot get the generic albuterol sulfate inhalation aerosol, the response they were to give was: “When a generic version is first available, it is typically similar in price to the brand version. At this time the generic version, called albuterol sulfate inhalation aerosol, is not on the formulary. You do have the option to request a formulary exception. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.”³⁹⁶ This was false. Keeping the brand as the only formulary choice would not have resulted in lower out-of-pocket costs for most beneficiaries in all stages and Medicare (payor) in the ICL and Catastrophic Coverage Stages and some scenarios for the Catastrophic Coverage Stage. Moreover, beneficiaries were discouraged from asking for a formulary exception by using the language “highest cost share level.”

633. When they were asked how long the brand-name Ventolin HFA would remain the only SilverScript formulary option, they were to tell beneficiaries: “We anticipate that VENTOLIN HFA will remain on the formulary on the Preferred Brand Tier (Tier 3) in 2019 until the price of the generic form of VENTOLIN HFA drops. We anticipate it will be a minimum of six months, however that is based on market conditions not within our control and could

³⁹⁵ *Id.*

³⁹⁶ *Id.*

change.”³⁹⁷

634. This was deceptive. By February 2019, the GoodRx price of the generic was \$52.13 compared to the brand Ventolin HFA price of \$63.29, already making the generic a lower cost option for both the beneficiary and Medicare. The decision to keep the brand Ventolin HFA as the only choice on the SilverScript formulary was not driven by market conditions, but CVS Health’s own profit motives. Likewise, it was a lie and deceptive to say that the market conditions were not “within our control” when it was CVS Caremark’s agreement with GSK that was the cause for the delay in the formulary access to the less costly generic drug albuterol sulfate inhalation aerosol. The market conditions were thus completely within its control.

635. When beneficiaries asked whether they could request a coverage determination to receive the less costly generic, SilverScript CCRs were expected to say: “Yes, you as the beneficiary may request a coverage determination for albuterol sulfate inhalation aerosol. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.”³⁹⁸ This was misleading and intended to discourage beneficiaries from asking for a formulary exception. A formulary exception for the generic albuterol sulfate inhalation aerosol would have been approved at the highest tier (Tier 4) which is the same tier/cost share 40% as the brand.

3. Beneficiary No. 12

636. On February 9, 2019 (two days after the Ventolin HFA scheme started), Beneficiary No. 12 (a 74-year-old woman from Michigan) filled a prescription for the generic albuterol HFA at her pharmacy. Her copay was \$18.89 and plan cost was \$28.34. The claim record shows that

³⁹⁷ *Id.*

³⁹⁸ *Id.*

her pharmacy filled Beneficiary No. 12's prescription and submitted the claim with DAW Code 0.³⁹⁹

637. Shortly thereafter, she received a letter from SilverScript dated February 12, 2019, stating that the Transition Fill of the generic was only a one-time fill because the drug was not covered on the formulary.⁴⁰⁰

638. When she later filled the Ventolin HFA prescription, the claim record shows that her pharmacy filled her Ventolin HFA prescription and submitted the claims with a "2 – PATIENT" code, indicating that the patient had requested the brand.⁴⁰¹

639. Here, as evidenced by Beneficiary No. 12's prior use of the generic, there is little reason to believe she had actually requested the brand Ventolin HFA, but was required to choose the brand because CVS Health did not include the generic on its formulary. Thus, a DAW 2 code in the PDE record in support of the SilverScript payment for Beneficiary No. 12 was untruthful, inaccurate and incomplete.

640. Furthermore, because her Ventolin HFA prescription was filled at a pharmacy located in Michigan, where state law requires that the pharmacy must dispense the generic when the patient requests it (MCL 333.17755), CVS Health violated the State law requirement that the prescription be substituted with a less costly generic.

4. CVS Health Rejected Thousands of Beneficiaries from Receiving Access to the Less Costly Generic Ventolin HFA (albuterol sulfate inhalation aerosol)

641. Following the implementation of the SSG/DNS Scheme for Ventolin HFA, CVS Health has routinely rejected thousands of beneficiary attempts to obtain access to the less costly

³⁹⁹ Exhibit 62 (CVS-002814).

⁴⁰⁰ Exhibit 63 (CVS-002809).

⁴⁰¹ Exhibit 64 (CVS-002813).

generic.

642. Attached hereto as Exhibit 65 is a representative sampling of 502 patients who sought access to the less costly generic albuterol sulfate inhalation aerosol through a Transition Fill between February 7, 2019 and February 13, 2019, the first week of the SSG/DNS Scheme, only to have their subsequent claims blocked in favor of the much more expensive brand-name Ventolin HFA. The list includes 165 patients where the prescription would have been filled in a mandatory substitution State.

643. Each of these beneficiaries was sent CVS Health's Transition Fill letter, stating that the Transition Fill of the generic was only a one-time fill because the drug was not covered on the formulary, and was required to use the brand Ventolin HFA thereafter.

644. The result of this charade not only deceived beneficiaries, it resulted in significant increased profits to CVS Health while dumping huge additional costs onto taxpayers and Part D beneficiaries, thereby violating the FTC Consent Order that it would not, directly or indirectly, make deceptive claims about the price or cost of Medicare Part D prescription drugs.

G. Canasa Rectal Suppository

645. Mesalamine rectal suppository or is used to treat inflammatory bowel disease, including ulcerative colitis and Crohn's disease. Allergan manufactures mesalamine rectal suppositories under the brand-name Canasa rectal suppositories 1000 mg.

646. Canasa is manufactured by Aptalis Pharma, a wholly owned subsidiary of Allergan, now owed by AbbVie.

647. On November 11, 2015, Aptalis entered into a pay-for-delay settlement agreement resolving patent infringement litigation with Mylan. Under the terms of the settlement agreement, Mylan would be able to launch its generic version of Canasa on December 15, 2018, or earlier under certain circumstances. Aptalis also entered into settlement agreements with Sandoz, PSP,

Inc., and Zydus, allowing them to begin marketing generic versions of Canasa in June 2019.

648. Mylan began selling a generic of Canasa on December 17, 2018. Numerous other generics came on the market shortly thereafter.

649. CVS Caremark shortly thereafter entered into an agreement with Allergan, requiring that SilverScript add Canasa to the SSG/DNS Scheme on February 22, 2019, blocking access not only to the authorized generic, but to all other generics on that market.

1. SilverScript Blocked Access to the Less Costly Generic Canasa (mesalamine-sofoamine)

650. SilverScript CCRs were provided materials and training telling them to explain the situation to beneficiaries as follows:

During the initial launch phase for the generic, there will be few manufacturers marketing the generic and the cost of the generic is expected to be relatively high. To help keep out-of-pocket costs low, SilverScript is retaining brand CANASA® RECTAL SUPPOSITORY on its formulary on Non-Preferred Drug Tier (Tier 4). CANASA is eligible for a manufacturer discount in the coverage gap. SilverScript will continue to keep the brand version of CANASA RECTAL SUPPOSITORY on the formulary and will NOT be adding the generic version until further notice.⁴⁰²

The CCR statement about cost of the generic mesalamine rectal suppository was false. The generic drug option(s) were lower cost to the member and Medicare Part D than the brand Canasa.

651. SilverScript CCRs were also to tell members that:

Retaining brand CANASA RECTAL SUPPOSITORY on Non-Preferred Drug Tier (Tier 4) can help keep out-of-pocket costs low for SilverScript beneficiaries. NOTE: The generic equivalent mesalamine rectal suppository is NOT on the formulary until further notice.

- Beneficiaries have the option to request an exception if they wish to obtain mesalamine rectal suppository.
- However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share

⁴⁰² Exhibit 66 CVS-000562-572).

level.

- Brand CANASA RECTAL SUPPOSITORY is available at the Non-Preferred Drug Tier (Tier 4) copay/coinsurance, so if the request for the generic is granted, the beneficiary would pay the amount associated with the plan's exception tier. This may be a different cost than the brand.⁴⁰³

The statement in the CCR script about keeping out-of-pocket costs low was false. Canasa was at the time a Tier 4 drug. A formulary exception would also have been approved for Tier 4. Keeping the brand-name drug as the only SilverScript formulary option would not have resulted in lower out-of-pocket costs. In addition, telling beneficiaries that a formulary exception would be at the “highest cost share level” was intended to discourage them from asking for the exception. This was deceptive. A formulary exception would also have been available with the Tier 4 coinsurance, almost always resulting in a lower cost for the generic.

652. If SilverScript CCRs were asked whether the Canasa Rectal Suppository would ever cost more at any stage for LIS beneficiaries, they were to respond:

Maybe. In the Catastrophic Coverage Stage of the benefit, you will continue to receive CANASA RECTAL SUPPOSITORY at no cost. If you have not yet reached the Catastrophic Coverage Stage, you might have to pay your brand-name copayment for CANASA RECTAL SUPPOSITORY until you reach the Catastrophic Coverage Stage.⁴⁰⁴

This was misleading because comparative costs are not provided to subsidy members, leaving them without information to determine actual cost differences. If they had been truthful, SilverScript CCRs would have told LIS beneficiaries:

- The cost to LIS 1 beneficiaries in the initial coverage stage for CY2019 is \$8.50 for the brand and \$3.40 for the generic mesalamine rectal suppository. Beneficiaries will pay \$0

⁴⁰³ *Id.*

⁴⁰⁴ *Id.*

for both the brand and the generic in the Catastrophic Coverage stage.

- Medicare Part D will pay \$418.22 for the brand (\$426.72 - \$8.50) and \$312.87 for the generic mesalamine rectal suppository (\$316.27 - \$3.40) in the ICL stage.
- Medicare Part D will pay \$258.20 for the brand (\$266.70 - \$8.50) and \$289.25 for the generic (\$292.55 - \$3.40) for the generic mesalamine rectal suppository in the Coverage Gap (where applicable).
- Medicare Part D will pay \$53.34 for the brand and \$39.53 for the generic mesalamine rectal suppository in the Catastrophic Coverage stage (full amount of beneficiary's cost) in addition to 80% of the cost of either drug for the Medicare portion of the cost of the drugs in this stage.

653. If they were asked why the brand Canasa Rectal Suppository is only choice on the SilverScript formulary when there is a generic mesalamine rectal suppository available, SilverScript CCRs were to respond:

In this case, the price of the generic version of CANASA RECTAL SUPPOSITORY will likely be similar to the price of the brand version for a minimum of six months, and perhaps longer. There are few manufacturers of the generic version of CANASA RECTAL SUPPOSITORY to drive the price down. Until there are competitors and the price of the generic version goes down, your plan will continue to cover brand-name CANASA RECTAL SUPPOSITORY at the Non-Preferred Drug Tier (Tier 4) cost share in 2019.⁴⁰⁵

The CCR statement about how long it will take for the generic mesalamine rectal suppository price to come down was false. The generic mesalamine was already much lower in price for most beneficiaries. There was no need to wait for there to be multiple generic manufacturers to drive the price down.

⁴⁰⁵ *Id.*.

654. If asked why they could not get a generic, SilverScript CCRs were directed to say:

At this time the generic version, called mesalamine rectal suppository, is not on the formulary. You do have the option to request a formulary exception. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.⁴⁰⁶

This was misleading. While this statement may have been true for some newly released generics, the generic for Canasa had been on the market for almost three years and was available at a lower cost option for beneficiaries. The CCR statement about the exception requests is a lie intended to discourage beneficiaries from asking for a formulary exception. A formulary exception for the generic mesalamine rectal suppository would have been approved at the highest tier (Tier 4) which is the same tier/cost share 34% as the brand.

655. If asked how long the brand Canasa would be the only SilverScript formulary option, they were expected to respond:

We anticipate that CANASA RECTAL SUPPOSITORY will remain on the formulary on the Non-Preferred Drug Tier (Tier 4) in 2019 until the price of the generic form of CANASA RECTAL SUPPOSITORY drops. We anticipate it will be a minimum of six months, however that is based on market conditions not within our control and could change.⁴⁰⁷

656. The CCR statement about generic pricing was misleading. By February 2019, the GoodRx price of the generic was \$332.75 compared to the brand Canasa price of \$1,213.43, already making the generic a lower cost option for both the beneficiary and Medicare Part D.

657. The decision to keep the brand Canasa Rectal Suppository as the only choice on the SilverScript formulary was not driven by market conditions, but by CVS Health's own profit motives. Likewise, it was a lie and deceptive to say that the market conditions were not "within

⁴⁰⁶ *Id.*

⁴⁰⁷ *Id.*

our control” when it was CVS Caremark’s agreement with Allergan that was the cause for the delay in the formulary access to the less costly generic drug mesalamine rectal suppository. The market conditions were thus completely within its control. Moreover, given the fact that there were as of 2019 seven competing generics (Amneal, Amring, Annora, Mylan, Pharmaceutical Sourcing Partners, Sandoz, Zydus), there was simply no reasonable explanation (other than greed) why Canasa remained the only SilverScript formulary option.

658. If beneficiaries asked whether they could submit a coverage determination for the generic, they were to respond: “Yes, you as the beneficiary may request a coverage determination for mesalamine rectal suppository. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.” This was deceptive and intended to discourage beneficiaries from asking for a formulary exception. A formulary exception for the generic would have been approved at the highest tier (Tier 4) which is the same tier/cost share 40% as the brand.

2. Beneficiary No. 13

659. Even for those who were explicitly looking for less costly options, CVS Health concealed information about a beneficiary’s right to request the generic version and has flatly misinformed them that there are no other options.

660. For example, Beneficiary No. 13 (a 65-year-old woman) was a cost-conscious senior from the beginning looking for less costly options. When Beneficiary No. 13 first called to submit her prescription for Canasa to the pharmacy, she was told that Canasa would cost her \$1,711 out of pocket. In response, Beneficiary No. 13 exclaimed “God, that’s terrible, I mean, I’m on Medicare and stuff.” Beneficiary No. 13 flatly said that she “can’t afford a thousand dollars.”⁴⁰⁸

⁴⁰⁸ Exhibit 67 CVS-001526.

661. Even after being transferred yet again, Beneficiary No. 13 was not told about her option to apply for a coverage determination for the formulary exception. Instead of telling her that a formulary exception might be available, the SilverScript CCRs discussed Beneficiary No. 13's options to apply for Medicare subsidy (Extra Help) or to look for a manufacturer discount (even though the manufacturer discounts were of no use because they cannot be used with Medicare).⁴⁰⁹

662. Throughout the calls, all of the SilverScript CCRs should have been able to see that there was an alternative and should have known that Beneficiary No. 13 had the right to request a coverage determination for the formulary exception for any drugs that are not covered by the PDP.

663. These were clearly requests for a formulary exception. However, it would appear SilverScript did not want them filed so it could conceal the SSG/DNS Scheme.

664. Eventually, CVS Health's efforts prevailed and Beneficiary No. 13 gave up trying to get less costly options. As Beneficiary No. 13 said: "I mean, 'I'm gonna have to pay it. One way or the ... If I'm gonna continue on the Canasa, I'm gonna have to pay it.... Right now, it's over \$1700 for a 3-month supply, which people can't afford that!'"⁴¹⁰

665. A large part of her motivation for giving in to the higher price was that her doctor told her she may develop cancer without the drug. As Beneficiary No. 13 explained to the SilverScript CCRs: "I know I have to take [Canasa] because she [her doctor] said it could develop into cancer if I didn't take it." Even this did not deter CVS Health.⁴¹¹

⁴⁰⁹ *Id.*

⁴¹⁰ Exhibit 68 (CVS-001553).

⁴¹¹ Exhibit 69 (CVS-001568).

666. Throughout, Beneficiary No. 13 repeatedly told the representatives that her doctor had let her know that Canasa (a drug she had been taking for 10 to 15 years) was her only alternative, mentioning that her prescription had run out three weeks before. She repeatedly told the representatives she could not afford her copay, and would have to consider skipping doses instead of using it daily as required.

667. This is non-compliant with CMS rules and regulations, and was by definition a coverage determination request for the generic Canasa. What happened to Beneficiary No. 13 is exemplary of thousands of instances where SilverScript denied beneficiaries access to their rights under Medicare.

668. Beneficiary No. 13's story shows the impact of CVS Health's scheme to make sure that its beneficiaries only had access to the brand-name version of the SSG/DNS Drugs. Even though Beneficiary No. 13 was an elderly beneficiary who battled through multiple phone transfers between different SilverScript CCRs (all of whom she told she could not afford the medication that she needed to prevent developing cancer), the CCR response was the same. No one at CVS Health gave her any less costly options which should have been readily available.

669. In addition to failing to provide Beneficiary No. 13 information about availability and cost of lower-priced generic options, her Canasa prescription was filled in a violation of State law requiring generic substitution. The claim record shows that CVS Caremark Prescription Service WBP, was located in Pennsylvania, a mandatory substitution State, filled Beneficiary No. 13's Canasa prescription and submitted the claim with DAW Code 0.⁴¹²

670. While Code 0 is the "default," NCPDP makes clear that, for "a multi-source

⁴¹² Exhibit 70 (CVS-001788).

branded product with available generic(s), *DAW 0 is not appropriate, and may result in a reject.*” (emphasis added)

671. CVS Caremark’s own “Caremark Participating Pharmacy Administrative Manual” includes guidance on DAW Codes as well. As the manual says, “CAREMARK supports the NCPDP standard (Dispense As Written) DAW codes. To ensure accurate reimbursement, always include the correct (DAW) code when you submit a claim.”⁴¹³

672. By not substituting the less costly generic version of the prescription, CVS caused false claims to be submitted in two ways: (1) the unsubstituted claims are invalid prescriptions under Pennsylvania state mandatory substitution law and thus not eligible for reimbursement by the SilverScript PDP, and (2) using DAW Code 0 in this instance makes the PDE record and statement in support of the SilverScript payment untruthful, inaccurate and incomplete.

3. Beneficiary No. 14

673. On March 20, 2019, Beneficiary No. 14 (a 62-year-old male paraplegic) called Customer Care to ask about the high cost of Canasa Suppositories. Beneficiary No. 14 explained to the CCR that the high cost of the medication had prevented him from filling his prescription previously (“And so, at first, I just didn’t get it filled because I couldn’t afford it.”). Despite his cost concerns, Beneficiary No. 14 indicated that he needed the medication because other forms of the medication (*i.e.*, an enema) would not work for him as a wheelchair-bound paraplegic and has “a lot of medical things.”⁴¹⁴

674. On the call, Beneficiary No. 14 said that he wanted to know why his previous efforts to fill his prescription for mesalamine rectal suppository (the generic version of Canasa) were

⁴¹³ Exhibit 1 (CVS-002944).

⁴¹⁴ Exhibit 71 (CVS-001578).

rejected. The CCR merely said that there is a note in the system to dispense the brand-name Canasa instead of the generic mesalamine rectal suppository. This was even though the claim detail screen in the Customer Care system specifically instructed the SilverScript CCRs to “DISCUSS GNRC SAVINGS OPPORTUNITY W/MBR.”⁴¹⁵

675. These conflicting instructions in the CCR script show how the systems used at CVS Health were often not in alignment given the multiple business units involved. In some areas of its CVS Health claims system, the representatives could see that less costly generics were available, but in other areas they were seeing that the brand-name SSG Drug should be dispensed and/or the generic is not covered. The sheer confusion of this environment acted as a barrier to beneficiaries getting clear options and information about overall cost impact.

676. Instead of working to help Beneficiary No. 14 get the appropriate medication at a price he could afford, the CCR only offered asking for tiering exception to try to get the brand-name Canasa at a less costly price. But, Canasa is not eligible for a tiering exception so this request was ultimately denied.⁴¹⁶ When Beneficiary No. 14 contacted CVS Health yet again, he was told that the generic mesalamine was not covered under his SilverScript plan.

677. Again, despite numerous opportunities, Beneficiary No. 14 was never told about the option to request a coverage determination to get a formulary exception. This deception ensured that only the brand-name medication would get filled at an plan cost of \$644.32 and patient copay of \$527.16.

678. This is non-compliant with CMS rules and regulations, and was by definition a

⁴¹⁵ Exhibit 72 (CVS-001800).

⁴¹⁶ Exhibit 71 (CVS-001578).

coverage determination request for the generic Canasa. What happened to Beneficiary No. 14 is exemplary of thousands of instances where SilverScript denied beneficiaries access to their rights under Medicare.

H. Advair Diskus

679. Fluticasone-salmeterol inhalation powder is used to control and prevent symptoms (wheezing and shortness of breath) caused by asthma or ongoing lung disease (chronic obstructive pulmonary disease-COPD, which includes chronic bronchitis and emphysema). It contains 2 medications: fluticasone and salmeterol. GSK manufactures fluticasone-salmeterol inhalation powder under the brand-name Advair Diskus.

680. Asthma impacts more than 20 million adults and 6 million children in the United States.⁴¹⁷ Since its arrival on the market in 2001, by 2018 Advair Diskus had surpassed \$100 billion in sales for GSK.⁴¹⁸ Though the medication's patent had expired in 2010, the company protected its blockbuster drug by obtaining patents on the diskus delivery system.⁴¹⁹

681. Keeping Advair Diskus as the only SilverScript formulary option for SilverScript beneficiaries has had a direct impact on patient care. The price of Advair Diskus — often more than \$300 a month — has meant that many patients often cannot afford the drug. When patients have been forced to skip doses because they cannot afford the cost of Advair Diskus, that means

⁴¹⁷ Centers for Disease Control and Prevention, https://www.cdc.gov/asthma/most_recent_national_asthma_data.htm.

⁴¹⁸ James Paton, *Glaxo's Advair Is the \$100 Billion Asthma Drug That Won't Die*, Bloomberg (May 4, 2018), <https://www.bloomberg.com/news/articles/2018-05-04/glaxo-s-advair-is-the-100-billion-asthma-drug-that-won-t-die>.

⁴¹⁹ Ben Hirschler, *In fight for GSK's Advair, generic firms step carefully on price*, Reuters (June 3, 2016), <https://www.reuters.com/article/us-gsk-advair/in-fight-for-gsks-advair-generic-firms-step-carefully-on-price-idUSKCN0YP1E0>.

more emergency room visits, use of powerful “rescue” medications and hospitalizations, said Christopher Fanta, a lung specialist at Harvard-affiliated Brigham & Women’s Hospital in Boston.⁴²⁰

682. On January 30, 2019, the FDA approved Mylan’s first generic version of Advair Diskus.⁴²¹ Mylan launched its generic on February 12, 2019.⁴²²

683. On February 8, 2019, GSK announced that Prasco had launched an authorized generic version of its Advair Diskus.⁴²³ As part of the launch, Prasco stressed the identical nature of the authorized generic product: ““The Prasco authorized generic, fluticasone propionate and salmeterol Inhalation Powder will provide patients with the same quality and experience as the brand product. A unique and exciting part of this launch is that the DISKUS inhaler itself will also be identical. . . . We are grateful to expand our relationship with a leader in the industry like GSK.”⁴²⁴

⁴²⁰ James Paton, *Glaxo's Advair Is the \$100 Billion Asthma Drug That Won't Die*, Bloomberg (May 4, 2018), <https://www.bloomberg.com/news/articles/2018-05-04/glaxo-s-advair-is-the-100-billion-asthma-drug-that-won-t-die>.

⁴²¹ See Press Release, *FDA approves first generic Advair Diskus* (Jan. 30, 2019), <https://www.fda.gov/news-events/press-announcements/fda-approves-first-generic-advair-diskus>.

⁴²² Press Release, *Mylan Launches Wixela™ Inhub™ (fluticasone propionate and salmeterol inhalation powder, USP), the First Generic of ADVAIR DISKUS® (fluticasone propionate and salmeterol inhalation powder), at a List Price 70% Less than the Brand* (Feb. 12, 2019), <https://investor.mylan.com/news-releases/news-release-details/mylan-launches-wixelatm-inhubtm-fluticasone-propionate-and>.

⁴²³ Prasco Laboratories, available at [https://prasco.com/news/2019/prasco-launches-the-authorized-generic-of-advair-diskus-\(fluticasone-propionate-and-salmeterol-inhalation-powder\).html](https://prasco.com/news/2019/prasco-launches-the-authorized-generic-of-advair-diskus-(fluticasone-propionate-and-salmeterol-inhalation-powder).html).

⁴²⁴ *Id.*

684. At the time, Mylan's competing generic was priced on GoodRx at \$135.74 compared to \$421.27 for the brand, 70% less than Advair Diskus and 67% less than GSK's authorized generic product.⁴²⁵

685. CVS Caremark shortly thereafter entered into an agreement with GSK, requiring that SilverScript add Advair Diskus to the SSG/DNS Scheme on February 27, 2019.

1. SilverScript Deception Blocked Access to the Less Costly Generic Advair Diskus (fluticasone propionate and salmeterol inhalation powder)

686. When Advair Diskus was added to the SSG/DNS Scheme, SilverScript CCRs were trained to tell beneficiaries that keeping the brand-name as the only SilverScript formulary option would keep out-of-pocket costs low:

Generic prescription drugs are typically the lowest-cost option when compared to branded prescription drugs. SilverScript promotes the use of generic prescription drugs to help plan beneficiaries save money. During the initial launch phase for the generic, there will be few manufacturers marketing the generic and the cost of the generic is expected to be relatively high. To help keep out-of-pocket costs low, SilverScript is retaining brand ADVAIR DISKUS® INHALATION AEROSOL POWDER BREATH ACTIVATED on its formulary on Preferred Brand Tier (Tier 3). ADVAIR DISKUS is eligible for a manufacturer discount in the coverage gap.⁴²⁶

This is misleading. Authorized generics are eligible for the Coverage Gap discount program since they are NDA "applicable" drugs.⁴²⁷ The generic drug option(s) were lower cost to the member and Medicare in the Coverage Gap (where applicable) and Catastrophic Coverage Stages.

⁴²⁵ Kristen Coppock, *Generic Version of Advair Diskus Launched at Discounted List Price*, Pharmacy Times (Feb. 13, 2019), <https://www.pharmacytimes.com/view/generic-version-of-advair-diskus-launched-at-discounted-list-price>.

⁴²⁶ Exhibit 73 CVS-000515.

⁴²⁷ CMS, *Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance* (May 21, 2010), at 4.

687. SilverScript CCRs were also told to say:

Retaining brand ADVAIR DISKUS on Preferred Brand Tier (Tier 3) can help keep out-of-pocket costs low for SilverScript beneficiaries. . . . Beneficiaries have the option to request an exception if they wish to obtain fluticasone-salmeterol aerosol powder breath activated. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level. Brand ADVAIR DISKUS is available at the Preferred Brand Tier (Tier 3) copay/coinsurance, so if the request for the generic is granted, the beneficiary would pay the amount associated with the plan's exception tier. This may be a different cost than the brand.⁴²⁸

688. When beneficiaries inquire whether ADVAIR DISKUS will cost more than fluticasone-salmeterol aerosol powder breath activated in any stage of the Medicare D benefit, they were expected to provide the scripted misleading answer to LIS members: "Maybe. In the Catastrophic Coverage Stage of the benefit, you will continue to receive ADVAIR DISKUS at no cost. If you have not yet reached the Catastrophic Coverage Stage, you might have to pay your brand-name copayment for ADVAIR DISKUS until you reach the Catastrophic Coverage Stage."⁴²⁹ Because costs are not provided, beneficiaries are left without information to determine the actual impact. If SilverScript CCRs had provided a truthful response, they would have told LIS beneficiaries:

- The cost to LIS1/LICS2 beneficiaries in the initial coverage stage for CY2019 is \$8.50/\$3.80 for the brand and \$3.40/\$1.25 for the generic mesalamine rectal suppository.
- Beneficiaries will pay \$0 for both the brand and the generic in the Catastrophic Coverage stage.
- In ICL for LIS 1 & 2 in 2019, the brand would have been less expensive for Medicare Part

⁴²⁸ *Id.*

⁴²⁹ *Id.*

D.

- In Coverage Gap and Catastrophic coverage scenarios for LIS 1 & 2 in 2019, the generic mesalamine rectal suppository would have been less expensive for the beneficiary and Medicare.

689. When SilverScript CCRs were asked why brand-name Advair Diskus is still the only SilverScript formulary option when there is a generic available, they were trained to provide a false answer:

In this case, the price of the generic version of ADVAIR DISKUS will likely be similar to the price of the brand version for a minimum of six months, and perhaps longer. There are few manufacturers of the generic version of ADVAIR DISKUS to drive the price down. Until there are competitors and the price of the generic version goes down, your plan will continue to cover brand-name ADVAIR DISKUS at the Preferred Brand Tier (Tier 3) cost share in 2019.⁴³⁰

Mylan's generic fluticasone-salmeterol aerosol powder breath activated was, in fact, already much lower in price for beneficiaries in the Coverage Gap (where applicable) and Catastrophic Coverage Stages. There was no need to wait for there to be multiple generic manufacturers to drive the price down.

690. In response to inquiries about why beneficiaries could not get the generic, their canned response was misleading: "When a generic version is first available, it is typically similar in price to the brand version. At this time the generic version, called fluticasone-salmeterol aerosol powder breath activated, is not on the formulary. You do have the option to request a formulary exception. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level."⁴³¹ Mylan's generic fluticasone-

⁴³⁰ *Id.*

⁴³¹ *Id.*

salmeterol aerosol powder breath activated was already much lower in price for some beneficiaries in the ICL stage and all beneficiaries in the Coverage Gap (where applicable) and Catastrophic Coverage Stages. There was no need to wait for there to be multiple generic manufacturers. This response was also intended to discourage beneficiaries from asking for a formulary exception where the generic would be less expensive for many subsidy members in the Choice plan and all members in the Allure plan.

691. If the question was how long Advair Diskus would remain the only option on the SilverScript formulary, SilverScript CCRs were to say that “[w]e anticipate that ADVAIR DISKUS will remain on the formulary on the Preferred Brand Tier (Tier 3) in 2019 until the price of the generic form of ADVAIR DISKUS drops. We anticipate it will be a minimum of six months, however that is based on market conditions not within our control and could change.”⁴³²

692. This was misleading. As of February 2019, the GoodRx price of Mylan’s generic was \$135.74 compared to the price of the brand Advair Diskus of \$421.27, already making the generic a lower cost option for both the beneficiary and Medicare in the Coverage Gap (where applicable) and Catastrophic Coverage Stages.

693. The decision to keep the brand Advair Diskus as the only choice on the SilverScript formulary was not driven by market conditions, but by CVS Health’s own profit motives. As of February 12, 2019, there were two generics being sold competing against Advair Diskus (Prasco, Mylan). Even then the brand-name Advair Diskus remained the only choice on the SilverScript Choice and Plus formularies.⁴³³ Likewise, it was a lie and deceptive to say that the market

⁴³² *Id.*

⁴³³ See 2020 SilverScript Choice Comprehensive Formulary, available at https://www.silverscript.com/pdf/FORM_2020_CHOICE_EN.pdf; 2020 SilverScript Plus

conditions were not “within our control” when it was CVS Caremark’s agreement with GSK that was the cause for the delay in the formulary access to the less costly generic drug fluticasone-salmeterol aerosol powder breath activated. The market conditions were thus completely within its control.

694. When members asked whether they could request a coverage determination to receive the less costly generic, SilverScript CCRs were expected to respond: “Yes, you as the beneficiary may request a coverage determination for fluticasone-salmeterol aerosol powder breath activated. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.”⁴³⁴ This was misleading and intended to discourage beneficiaries from asking for a formulary exception which would help reduce the cost of the generic vs the brand in the Coverage Gap (where applicable) and Catastrophic Coverage Stages.

2. Beneficiary No. 15

695. Beneficiary No. 15 is an example of a senior determined to get the less costly Mylan generic Wixela because cost of the brand Advair Diskus would push her into the Part D Donut Hole. She was blocked by SilverScript at every turn. She was first told by the CCR she might be able to get a formulary exception for the generic (which turned out not to be true), then told that the Wixela might be more expensive for her (in fact, Wixela was 70% less costly than the brand), and finally told that the reason it was being blocked might be because it was unsafe (untrue).

696. On February 27, 2019, Beneficiary No. 15 (a 78-year-old retired nurse from

Comprehensive Formulary, available at https://www.silverscript.com/pdf/FORM_2020_PLUS_EN.pdf.

⁴³⁴ Exhibit 73 (CVS-000512-23).

Massachusetts) had contacted SilverScript Customer Care and spoken with CCR Kandace Thomas. Beneficiary No. 15 had earlier that day attempted get the generic Advair Diskus at her pharmacy, but was told it was not covered on her formulary. During the call she asked the CCR specifically why SilverScript would not give her access to the generic manufactured by Mylan, Wixela, because she wanted to reduce her costs to avoid going into the Donut Hole on her Medicare Part D plan. She objected to CVS Health blocking the generic because “that is wrong.” In response, CCR Thomas told her she might be able to get a formulary exception because the generic is not covered⁴³⁵:

Beneficiary No. 15: Okay. I went to get my Advair Diskus, and **I know that there's a generic available and it seems like SilverScript is not covering the generic and because it's not on the formulary and that is wrong.** And I would like the Wixela.

Kandace Thomas: Okay. So you would prefer the generic?

Beneficiary No. 15 : Yes. **The pharmacy is supposed to offer me the generic versus the preferred brand and the SilverScript should not have anything to do with my preference with, especially when there's a generic available. . . . And another thing is the cost probably will be less costly and I won't go in the Donut Hole maybe.**

Kandace Thomas: Okay. Well, in this case, let's see. This brand, yeah so the generic is not on the formulary. And so I'm looking at it now and I do see here that the generic is not on the formulary. So in this case, the brand is preferred. In some cases they prefer the generics, but in this case, the brand is preferred. So are you wanting to see about trying to get the generic?

Beneficiary No. 15: Yes. Yes.

Kandace Thomas: Okay. So let's see. Okay. All right. So that would require, **so what'll have to happen is called a formulary exception since this one is not on the formulary. We'll have to start the process to try and get this particular one on the formulary in your case.** Okay. So that means I have to get

⁴³⁵ Exhibit 74 (CVS-003007).

our Care Exception Review Team on the line. They'll speak with you, and then they'll get our Coverage Determination Team. And they'll let you know the steps from there. Okay?

697. CCR Thomas then discussed offline Beneficiary No. 15's request with Keonna Harmon on the Coverage Exceptions Review team, who explained that the generic was not available because "anytime they say dispense brand, it's something going on with that medication"⁴³⁶:

Kandace Thomas: She was trying to get her WIXELA INHUB filled, but she was told at the pharmacy that she had to use the brand-name, which [is] ADVAIR DISKUS. She's really upset about that. She wants to use the generic. She's wanting to get an exception on that one.

Keonna Harmon: **She cannot use that medication. She has to use the brand. That's why it's saying dispense her the brand.**

Kandace Thomas: She was saying it's wrong, and you can't tell me what to buy. She absolutely cannot get an exception on that WIXELA?

Keonna Harmon: No. That one, that medication, **anytime they say dispense brand, it's something going on with that medication.**

698. CCR Thomas then went back on the line with Beneficiary No. 15 to tell her that her formulary exception request for Mylan generic would be denied, repeating CER Harmon's statement that "there's something going on with the generic"⁴³⁷:

Kandace Thomas: Yes. So I got the Care Exception Review Team on the line. And when I explained to them what was going on, you were wanting to get the Wixela covered, **she had let me know that in cases where the note says dispense brand, you have to get the brand.** She said **there's no way you can get a formulary exception on that**, because it's specifically saying. She said normally when they say that, that means **there's something going on with the generic.** So they prefer the brand.

⁴³⁶ Exhibit 75 (CVS-003011).

⁴³⁷ Exhibit 74 (CVS-003007).

699. To deflect the caller's concerns, CCR Thomas next explained to Beneficiary No. 15 that the generic would be more expensive than the brand Advair Diskus. However, Beneficiary No. 15 challenged that the cost of the generic was a plausible reason for blocking it, telling CCR Thomas that she has a friend who is getting the generic Wixela at a less costly price, commenting SilverScript "just doesn't want to change because it's to their benefit... I'm not feeling that they're thinking of the consumer and it's hard for me to believe that the generic is pricier than the Advair. It shouldn't be that way."⁴³⁸:

Kandace Thomas: And actually now that I'm doing it, that Wixela is way more expensive than the Advair. The Wixela is almost \$200.

Beneficiary No. 15 : \$200 for whom?

Kandace Thomas: For the Wixela, the generic.

Beneficiary No. 15 : I pay \$38 for Advair myself through SilverScript.

Kandace Thomas: Right.

Beneficiary No. 15 : The plan paid \$359.48.

Kandace Thomas: Yes ma'am.

Beneficiary No. 15 : What are you telling me?

Kandace Thomas: What I'm telling you is that the Wixela, if you were to get that one... you can't get an exception on it. But the only good thing with that is that if you were to pay for the Wixela, you're going to be paying \$128 for it. The brand is actually less costly.

Beneficiary No. 15 : I know somebody that gets it and they don't pay that.

Kandace Thomas: Well, they. . . .

Beneficiary No. 15 : Well, **it sounds like SilverScript just doesn't want to change because it's to their benefit. . . . I'm not feeling**

⁴³⁸ *Id.*

that they're thinking of the consumer and it's hard for me to believe that the generic is pricier than the Advair. . . . It shouldn't be that way. . . . Well, maybe according to SilverScript, because they want it to be.

700. Remarkably, CCR Thomas then ventured that there's "something going on" with the generic – *i.e.*, "where we don't want to give it to you" – which could be because it "may affect you," suggesting CVS was blocking the generic because of safety concerns⁴³⁹:

Kandace Thomas: **So if there's something going on where we don't want to give it to you, where it may affect you, then we're not going to. We don't want you to receive anything that's not**

701. This interchange illustrates the lengths to which CVS Health was willing to go in deceiving beneficiaries seeking access to less costly medications.

702. Because her request for a coverage determination for the 70% less costly generic Wixela had been rejected, Beneficiary No. 15 then relented and filled the Advair Diskus prescription at her local pharmacy with a \$38.00 copayment and \$359.48 plan cost.⁴⁴⁰

703. Not only that, because the prescription was filled at a pharmacy in Massachusetts, a mandatory generic substitution State, SilverScript violated the State law requirement that the prescription be substituted with a less costly generic.

3. SilverScript Deception Blocked Access to Thousands of Beneficiaries Seeking Access to Generic Advair Diskus

704. Following the implementation of the SSG/DNS Scheme for Advair Diskus, CVS Health has routinely rejected thousands of beneficiary attempts to obtain access to the less costly generic.

705. Attached hereto as Exhibit 77 is a representative sampling of 73 rejected

⁴³⁹ *Id.*

⁴⁴⁰ Exhibit 76 (CVS-001664).

SilverScript claims for generic Advair Diskus prescriptions for just one day, January 27, 2019, the day CVS Health initiated the SSG/DNS Scheme for this drug.

706. Each of these beneficiaries was sent SilverScript's letter denying formulary exceptions implemented for the Advair Diskus generic. Not one of these letters informed the recipients that the non-formulary generic Wixela was 70% less costly than the brand drug.

707. The formulary exception letter sent to beneficiaries rejecting their requests for the less costly generic tells them that they had the right to ask for an appeal of the denial of the formulary exception. What the letter failed to tell them was that the result of any appeal was already doomed to fail – *i.e.*, CVS Caremark had already agreed with GSK that SilverScript would summarily deny all appeals.

4. CVS Health Senior Management Deception About Its “Proven Cost Management Strategies” To Block Beneficiary Access to the Less Costly Generic Advair Diskus

708. Shortly before he testified before the Senate Finance Committee, on March 19, 2019, CVS Health Executive Vice President and President of CVS Caremark Derica Rice issued a briefing⁴⁴¹ discussing “new trends” in the pharmacy benefit market that require “ongoing innovation, and evolution of, cost management strategies.” Rice specifically mentioned the “increasing use of authorized generics” by manufacturers, stating that “[s]ome manufacturers have chosen to launch an alternative version of the brand product at a lower cost under a different National Drug Code (NDC), which enables them to continue marketing the brand at a higher price.”⁴⁴²

⁴⁴¹ Derica Rice, *Why the Time is Right for a New Pricing Model: As Market Trends Evolve, Payors Need an Adaptable Approach* (March 19, 2019), <https://payorsolutions.cvshealth.com/insights/why-the-time-is-right-for-a-new-pricing-model>.

⁴⁴² *Id.*

709. In a bit of sleight of hand, Rice touted that CVS Caremark was using its “proven cost management strategies and [has] negotiated with manufacturers to help ensure members had access to appropriate therapies while clients could focus on controlling plan costs.” Among the examples he mentioned where CVS Caremark had used its “formulary tools” to blunt the impact of drug maker gamesmanship was Advair Diskus. According to Rice, one opportunity for cost savings “came in the form of two new generics for Advair Diskus launching in February — an authorized generic by the maker of the brand drug and another one by a different manufacturer.”⁴⁴³

710. But, there were no “cost savings” in the offing for SilverScript beneficiaries. What Rice failed to mention was that three weeks earlier CVS Caremark had entered into an SSG/DNS deal with GSK, requiring that SilverScript block access to the 70% less costly generic Wixela, forcing beneficiaries instead to use only the much more expensive “appropriate” therapy, Advair Diskus. The result was sadly predictable, impeding access to the less costly generic and driving up costs for Medicare and Part D patients alike.

711. The result of this travesty not only deceived beneficiaries, it resulted in significant increased profits to CVS Health, while dumping huge additional costs onto taxpayers and SilverScript beneficiaries, thereby violating the FTC Consent Order that it would not, directly or indirectly, make deceptive claims about the price or cost of Medicare Part D prescription drugs.

X. COUNTS

COUNT I

(Violation of False Claims Act, 31 U.S.C. § 3729(a)(1); 31 U.S.C. § 3729(a)(1)(A))

712. Relator incorporates herein by reference the preceding paragraphs of this Second Amended Complaint as though fully set forth herein.

⁴⁴³ *Id.*

713. CVS Health, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the United States of America false or fraudulent claims for payment or approval, in violation of 31 U.S.C. § 3729(a)(1) and 31 U.S.C. § 3729(a)(1)(A).

714. As a result of CVS Health's actions, as set forth above, the United States of America has been, and may continue to be, severely damaged.

COUNT II
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(2); 31 U.S.C. § 3729(a)(1)(B))

715. Relator incorporates herein by reference the preceding paragraphs of this Second Amended Complaint as though fully set forth herein.

716. CVS Health, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements material to the payment of false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(2); 31 U.S.C. § 3729(a)(1)(B).

717. CVS Health's false and fraudulent statements, including with respect to the safety and efficacy, superiority, and medical necessity and appropriateness of its drugs, to the public, to patients, to the Health Care Providers, were material to the Health Care Providers' decisions to prescribe these drugs and the United States' decisions to pay claims for these drugs and related services.

718. The United States, unaware of the falsity of the claims and/or statements made by CVS Health, and in reliance on the accuracy of these claims and/or statements, paid and may continue to be paying or reimbursing for the Drugs prescribed to patients enrolled in Federal

Programs.

719. As a result of CVS Health's actions, as set forth above, the United States of America has been, and may continue to be, severely damaged.

COUNT III

(Violation of False Claims Act, 31 U.S.C. § 3729(a)(3); 31 U.S.C. § 3729(a)(1)(C))

720. Relator incorporates herein by reference the preceding paragraphs of this Second Amended Complaint as though fully set forth herein.

721. As alleged above, CVS Health and the SSG/DNS Scheme Drug Makers knowingly conspired, and may still be conspiring, to commit acts in violation of 31 U.S.C. §§ 3729(a)(1) & (a)(2); 31 U.S.C. §§ 3729(a)(1)(A) & (a)(1)(B). CVS Health and the SSG/DNS Scheme Drug Makers committed overt acts in furtherance of the conspiracy as alleged above.

722. As a result of CVS Health's and the SSG/DNS Scheme drug makers' actions, as set forth above, the United States of America has been, and may continue to be, severely damaged.

COUNT IV

(Violation of False Claims Act, 31 U.S.C. § 3729(a)(1)(G))

723. Relator incorporates herein by reference the preceding paragraphs of this Second Amended Complaint as though fully set forth herein.

724. As alleged above, CVS Health knowingly made, used, and/or caused to be made or used, false records or statements material to an obligation to pay or transmit money or property to the Government, and/or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government pursuant to § 3729(a)(1)(G).

725. As a result of CVS Health's actions as set forth above, the United States of America has been, and may continue to be, severely damaged.

PRAYER FOR RELIEF

WHEREFORE, Relator prays for judgment against CVS Health as follows:

A. That CVS Health be ordered to cease and desist from submitting or causing to be submitted any more false claims, or further violating 31 U.S.C. §§ 3729 *et seq.*;

B. That judgment be entered in Relator's favor and against CVS Health in the amount of each and every false or fraudulent claim, multiplied as provided for in 31 U.S.C. § 3729(a), plus a civil penalty of not less than eleven thousand one hundred eighty-one (\$11,181) or more than twenty-two thousand three hundred sixty-three dollars (\$22,363) per claim as provided by 31 U.S.C. § 3729(a)(1), to the extent such multiplied penalties shall fairly compensate the United States of America for losses resulting from the various schemes undertaken by CVS Health, together with penalties for specific claims to be identified at trial after full discovery;

C. That Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d).

D. That CVS Health be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct;

E. That judgment be granted for Relator against CVS Health for all costs, including, but not limited to, court costs, expert fees and all attorneys' fees and costs incurred by Relator in the prosecution of this suit;

F. That Relator be granted such other and further relief as the Court deems just and proper;

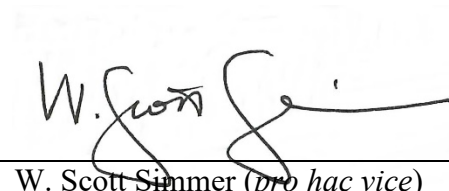
G. That the Court issue an order enjoining CVS Health from continuing to engage in the fraudulent conduct alleged herein; and

H. That this Court award such further relief as it deems just and proper.

JURY TRIAL DEMAND

Relator demands a trial by jury of all issues so triable.

Dated: February 23, 2022

A handwritten signature in black ink, appearing to read "W. Scott Simmer", is written over a horizontal line.

W. Scott Simmer (*pro hac vice*)
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Jennifer Connolly (*pro hac vice*)
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EXHIBIT 1

CAREMARK INC.

PARTICIPATING PHARMACY ADMINISTRATIVE MANUAL

Contents:

Introduction

Section 1: ON-LINE BILLING (Billing Guidelines)

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Section 1.4 Days Supply: The Need for Accuracy

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Introduction

The Caremark Pharmacy Administrative Manual (“Manual”) is intended to be a guide for retail pharmacists to assure the highest quality, efficient, and cost-effective Pharmaceutical Services are provided to Caremark Participants.

The defined terms in the Agreement will have the same meaning as used in this Manual. The Manual also provides the pharmacist basic information to prevent inappropriate billing practices and answers to common billing questions.

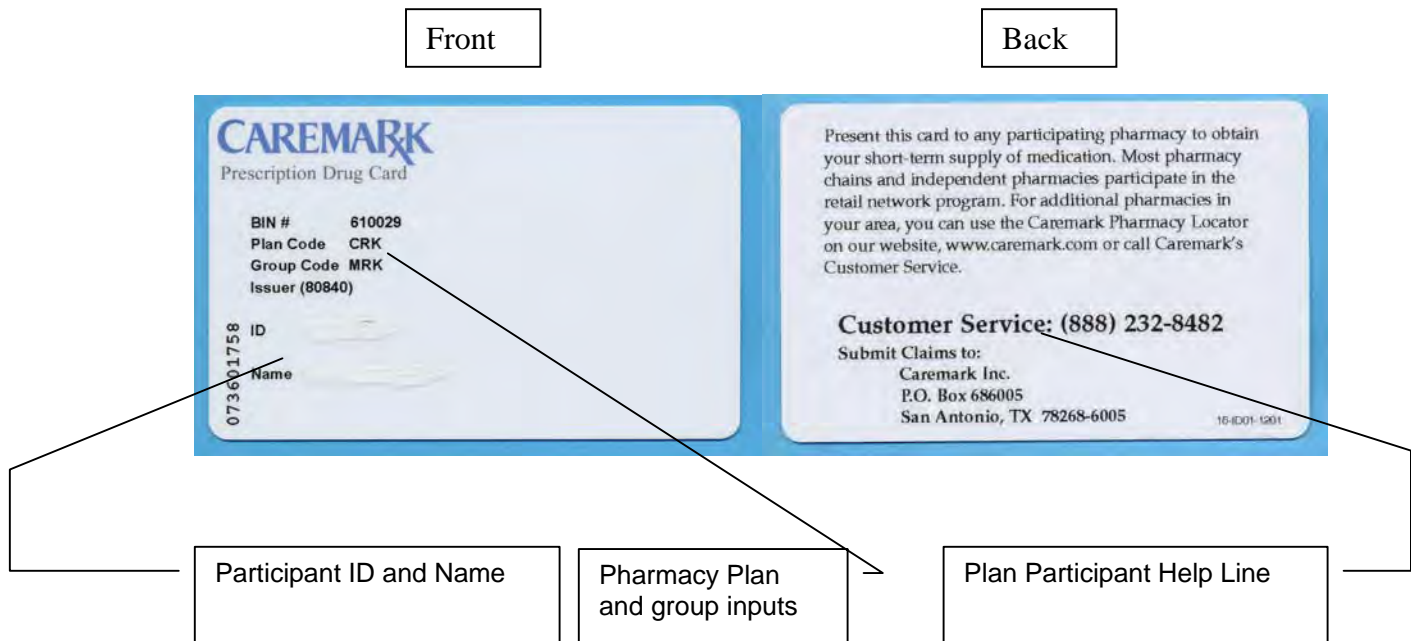
The Caremark Pharmacy Administrative Manual is not designed to cover all circumstances or issues, nor is it a replacement for sound clinical judgement. In the event that the manual and the Caremark Participating Pharmacy Agreement (“Agreement”) differ, the Agreement will supersede the Manual.

Although efforts are made to keep the information current, this Manual is subject to change without notice, and the latest version of the Manual will available at www.Caremark.com, click Healthcare Professionals, and then click on Retail Pharmacies. If there are any questions, please contact the retail pharmacy help desk at 1-800-421-2342.

Section 1: ON-LINE BILLING (Billing Guidelines)

1.1. Caremark Identification Card

The Caremark identification card is not a guarantee of Participant eligibility. Caremark has standardized its identification card format to assist Pharmacy in recognizing a Participant using Caremark's networks. Below is an example of a standard Caremark Identification card.



1.2. Programs with Deductibles or Maximums

Some Plans include a maximum benefit (when coverage stops) or require Participants to meet an annual deductible (before coverage begins). So that Caremark can accurately track an unpaid deductible, the pharmacist must transmit each claim via the on-line system. Caremark will reimburse the Pharmacy directly for claims transmitted, if claim submitted within 30 days of date of service, before a maximum benefit is diminished or after a Participant meets the deductible.

1.3. Plan Limitations

Claims submitted on-line which exceed Plan limits for days supply or quantity dispensed will reject with the message, PLAN LIMITATIONS EXCEEDED or similar language. The reject message may include the actual limits.

For example: Maximum days supply 30

Pharmacists are responsible for entering the correct days supply of medication. For example, the days supply for 25 doses of medication, taken 25 per month, is 30 days. The days supply for 4 patches, applied once weekly, is 28 days.

Example: Premarin 0.625 mg
Sig: 1 tab on days 1-25 each month
Disp: Number 25
This is a 30 days supply of medication.
Example: Lariam
Sig: One per week
Disp: Number 4
This is a 28-days supply of medication.

1.4. Days Supply: The Need for Accuracy

If the prescribing provider indicates, "as directed," you will need to determine the dosing schedule in order to submit the correct days supply with the claim. Talk with the Participant or call the Prescribing Provider to determine the appropriate amount to dispense. Claim reimbursement is based on quantity dispensed. Moreover, to provide appropriate pharmaceutical consultation, you must be sure the Participant understands how much and how often the medication is to be taken.

1.5. Submission of Insulin

Use actual NDC numbers of insulin dispensed.

Some Participants require two types of insulin (i.e., NPH or regular). Often both medications appear on the same prescription. Since each drug has a unique NDC number, separate the prescription into two claims, submit both and collect two copays.

1.6. Dispensing Limitations for Inhalers

When submitting a claim on-line, enter the quantity to be dispensed exactly as written by the Prescribing Provider on the prescription form. Dispensing limitations vary widely among Caremark Plans.

Depending on the Participant's medical condition, it may be necessary to dispense more than one inhaler. If Plan design limitations, allow and the Prescribing Provider writes accordingly, the Participant may obtain more than one inhaler per prescription.

1.7. Drugs with Unusual Submission Requirements

Claims for these drug products frequently result in incorrect reimbursement. To help avoid charge backs, see the following examples:

Drug Name	Unusual Features	Commonly Prescribed Dosage	Submit This Quantity To Caremark:	Corresponding Days Supply To Submit:
Elimite[®] Eurax[®] (Treatment of scabies)	May be ordered for all members of a family on 1 prescription blank	1 treatment course per person	Submit separate claim for each individual in family	Elimite: 1 Eurax: 2
Lariam[®]	Prophylaxis dosage: 1 tablet per week	4 tablets per month	4	28
Prevpac[®]	8 pills blister-packed on single card; 14 cards in each package	1 card per day for 14 days	14	14
Preven[®]	Kit with 1-day supply	2 tablets at once; 2 tabs 12 hours later	1	1
Pulmicort[®]	No gm indicated on inhaler or package label; 200 actuations contained in single inhaler	8 actuations per day	1	25
Xalatan Ophth Drops	Approx. 83 drops per vial	1 drop in each eye at bedtime	2.5 MDQ	30
Sporanox[®] (Pulse treatment for fingernails only)	Indicated as 2 treatment pulses, each consisting of 1 week of treatment and 3 weeks without drug.	2 capsules twice daily for 1 week at the beginning of each 4- week period.	28 Submit claim for refill for 2 nd month's treatment	28

1.8. Quantities

Using NCPDP Version 3.2A, both metric quantity (MQ) and metric decimal quantity (MDQ) can be sent. Using NCPDP Version 5.1 only the MDQ should be sent. The billed price must be accurate on a decimal quantity basis regardless of the quantity specified in the MQ field.

1.9. Claim Processing System Transmission Requirements

See Caremark's NCPDP version 5.1 payer sheet located on the Web at www.Caremark.com, then click **Healthcare Professionals**, and then click **Retail Pharmacy** for correct methods of claim submission.

1.10. Dispense as Written (DAW)

CAREMARK supports the NCPDP standard (Dispense As Written) DAW codes. To ensure accurate reimbursement, always include the correct (DAW) code when you submit a claim.

Claims submitted to Caremark with DAW codes of 3-6 or 8-9 will be adjudicated similarly to a DAW 0. If necessary, contact your software vendor for needed alterations to your pharmacy system.

Claims for code DAW 7 may reject as an "Invalid" DAW code. Contact the Prescribing Provider. to see if a generic can be dispensed. If the Prescribing Provider instructs you to dispense the brand, then submit the claim with a DAW 1 code or if the Participant indicates the desire for the brand, submit the claim with a DAW 2 code and note the outcome clearly on the hard copy of the prescription.

<u>Dispense As Written (DAW)</u>
DAW 0 - NO DISPENSE AS WRITTEN (Substitution Allowed) (or no product selection indicated) <ul style="list-style-type: none"> • Use the DAW 0 code when dispensing a generic drug; that is, when no party (i.e., neither Prescribing Provider, nor pharmacist, nor Participant) requests the branded version of a multi-source product. • Use the DAW 0 code when dispensing a multi-source generic, even if the Prescribing Provider indicates the DAW code for the generic product and does not specify a manufacturer. • Also, use the DAW 0 code when dispensing single-source brands (e.g., Lipitor[®]), because generic substitution is not possible.
DAW 1 – PHYSICIAN writes DISPENSE AS WRITTEN <ul style="list-style-type: none"> • Use when the Prescribing Provider specifies the branded version of a drug on the hard copy prescription or in the orally communicated instructions. • If Participant requests brand, and it is not a Prescribing Provider-initiated instruction, transmit the DAW 2 code. (See following instruction.)
DAW 2 - PATIENT REQUESTED <ul style="list-style-type: none"> • Use this code when the Participant requested the branded drug even though the original prescription did not indicate "Dispense As Written".
DAW 3 - PHARMACIST SELECTED BRAND
DAW 4 - GENERIC NOT IN STOCK

<u>Dispense As Written (DAW) continued</u>
DAW 5 - BRAND DISPENSED, PRICED AS GENERIC <ul style="list-style-type: none"> • Use when dispensing a brand as a generic. • Claims submitted with DAW 5 will be reimbursed at the generic price.
DAW 6 - OVERRIDE
DAW 7 - SUBSTITUTION NOT ALLOWED; BRAND MANDATED BY LAW
DAW 8 - GENERIC NOT AVAILABLE
DAW 9 - OTHER
Remember: Most Participants have a choice between brand and generic drugs. However, in some programs, the Participant will pay the difference between the cost of the brand and the available generic drug. Accordingly, correct DAW submissions indicate if a penalty is applicable.

1.11. Drug Utilization Review (DUR)

DUR edits are designed to support your professional role in providing quality care and clinical services to Participants whose prescription benefit is administered by Caremark.

When the DUR program detects a potential therapeutic problem for a Caremark claim, you will receive an on-line message via the on-line system. Thus, you have a professional obligation to and resolve a potential problem before dispensing the drug, which may require consulting the Prescribing Provider.

Patient drug profiles used for DUR analysis are developed from prescription records processed by Caremark. In this way, DUR helps to monitor therapeutic conflicts between the prescription you are currently filling and other prescriptions received by that Participant, which were processed by Caremark. It is extremely important to thoroughly document your DUR-related actions and subsequent Prescribing Provider comments and instructions. This is a permanent record of your professional follow-through in response to DUR messages.

1.12. Formulary Compliance

Pharmacy is notified via an on-line response when a claim is submitted for formulary and non-formulary products. If a non-formulary product is prescribed the Pharmacy should (upon consent of the Participant) contact the Prescribing Provider and request that the formulary product be prescribed.

1.13. NDC Number (National Drug Code)

Pharmacies should always submit to Caremark the exact 11-digit NDC number of the actual package size of the Product dispensed.

Section 2: AUDIT GUIDELINES

Caremark has the right to examine prescription information and other related information, during normal business hours as set forth in the Participating Pharmacy Agreement. If Caremark is denied admission to the Pharmacy or if Pharmacy does not present prescription records, signature logs and supporting documentation, Caremark has the right to charge back 100% of the reimbursed claims.

If Caremark selects your Pharmacy for an audit you will receive a notification letter approximately two weeks in advance. The notice may be closer to the date in certain circumstances.

Below is information to help you avoid problems and prepare for the audit.

2.1 Time Frame

The time frame for an audit may encompass all retained records; normally, an auditor will review claims dispensed during the past three years. Caremark will audit claims paid, not necessarily filled during the audit period in question.

2.2 Prescription Hard Copies

- 2.2.1 A hard copy of each prescription must be readily retrievable upon request.
- 2.2.2 Prescriptions for insulin and/or syringes must contain complete documentation of items and quantities dispensed.
- 2.2.3 Prescription hard copies must be updated yearly unless state pharmacy law in which Pharmacy is located specifically allows a prescription to be refilled after more than one year has passed.
- 2.2.4 A prescription hard copy must be maintained for every prescription for three years or longer as required by state law. The hard copy (original and any updates) of the prescription, including telephone prescriptions, must contain data elements required by state pharmacy laws in which Pharmacy is located and all of the Prescribing Provider's instructions—including DAW code instructions — that support your claim transmission.

2.3 Signature Log

- 2.3.1 Pharmacy shall require the signature of the Participant or the Participant's representative on a permanent record before dispensing any prescription.
- 2.3.2 At each Pharmacy location, Pharmacy shall maintain a hard copy or electronic signature log which states the following: (i) the prescription number; (ii) the date the Product is received by the Participant; and (iii) the

signature of each Participant who receives a Product or the signature of his/her designee.

2.3.3 A log in date order must be maintained for all claims submitted on-line to Caremark.

2.3.4 Signature logs must be maintained for three years or longer—corresponding to the state pharmacy laws in which Pharmacy is located for retaining prescription hard copies. The logs must be available for inspection and audit by a representative of Caremark and/or its designated agent.

2.4 Dispensing Limitations

2.4.1 Enter the quantity to be dispensed exactly as written on the prescription form.

2.4.2 A 30-day supply is no longer standard; some programs permit up to 90-day quantities. Always transmit the appropriate days supply and allow the on-line system to communicate the allowable days supply.

2.4.3 Note subsequent changes or refill authorizations approved by the Prescribing Provider on the hard copy, or in a readily retrievable electronic format, acceptable by the State Board of Pharmacy in which Pharmacy is located.

2.5 Customary Charge

Customary Charge means the usual and customary price charged by Pharmacy to the general public at the time of dispensing, including any advertised or sale prices, discounts, coupons or other deductions.

2.6 Dispense As Written (DAW) Audit Issues

2.6.1 Incorrect DAW codes are the most common cause of pharmacy charge backs and may lead to removal from the network.

2.6.2 When an auditor cites a prescription for a missing or incorrect DAW code, follow-up documentation is not permitted.

2.6.3 A transmitted DAW 1 code must be supported on the prescription hard copy (original and update).

2.6.4 No DAW 1 code defaults should be set.

2.6.5 A DAW 2 code should be transmitted when the Participant requests that the Prescribing Provider be contacted to obtain approval for a brand drug when the Prescribing Provider did not initially mandate dispense as written.

2.7 Miscellaneous

- 2.7.1 Claims are adjudicated based on data provided to Caremark. If a claim is adjudicated based on incorrectly submitted data, an adjustment may be necessary.
- 2.7.2 Transmit the data as listed on the prescription and as ordered by the Prescribing Provider. Proper submission of days supply, quantity (obtain and document "as directed" instructions), NDC number, eligibility information, etc.
- 2.7.3 Transmit DAW 1 code only when initially authorized by the Prescribing Provider; the prescription hard copy (including hard copies documenting phoned-in prescriptions) must support a DAW 1 code.
- 2.7.4 Obtain a signature on the signature log.
- 2.7.5 Reverse claims that are not dispensed to the Participant or their designated agent.
- 2.7.6 Transmit proper Participant information, including relationship code, sex and proper Prescribing Provider identification number.
- 2.7.7 Pharmacy must charge the Participant the Co-payment amount indicated in the on-line response.
- 2.7.8 Pharmacy has 14 days from the receipt of the audit report to provide appropriate documentation to justify the audit discrepancies identified in the audit, pursuant to audit guidelines.
- 2.7.9 Caremark may deny payment for unsupported claims or missing signatures.
- 2.7.10 Caremark may satisfy an unpaid audit liability by any of the following methods which may include but are not limited to: request for a check, offset against future claims payment and use of a collection agency.
- 2.7.11 Caremark has the right to assess reasonable fines, penalties and fees to cover unexpected costs.

Section 3 Submitting Compounds

One of the items in the compound must be a legend drug. Caremark does not accept invalid NDCs for any compounds. When prompted for the NDC number, enter the NDC number of the most expensive legend drug in the compound per unit (capsule, tablet, gram, or ml). When prompted for quantity, enter the total quantity of the final product dispensed.

When submitting for ingredient cost, enter the combined cost of all ingredients. The combined cost shall not include labor costs, equipment costs, delivery charges, professional fees, etc.

As with all claims, submit Pharmacy's Customary Charge.

To prevent audit charge backs, make sure your software is not programmed to place an amount in the ingredient cost field that is equal to the AWP of the most expensive NDC multiplied by the final product quantity.

Change the compound indicator to indicate that the prescription is a compound. Powdered oral antibiotics that are mixed with distilled or tap water are not considered compounds.

3.1 Progesterone Compounds

Caremark does not allow the use of invalid NDC numbers for progesterone suppositories, suspensions and vaginal capsules used in compounding. Use the actual NDC number and submit the claim as you normally submit a compound.

Section 4: Caremark Help Desk

The Caremark pharmacy help desk is available 24/7/365 days a year with regularly scheduled down times.

The phone number is 1-800-421-2342.

EXHIBIT 2

Welcome back, [Alexandra!](#) ([Log out](#))

advocacy network

About Our Priorities

Affordable Medication

By increasing competition, we can keep drug costs low, making sure our patients can afford to take their medications and stay healthy.

Get Involved **FAQ**



At CVS Health, we believe common sense, market-oriented reforms that promote competition are key to making prescription drugs affordable and reducing overall health care costs. Healthy competition in the pharmaceutical industry, it allows us to negotiate lower prescription drug prices and give less expensive, clinically-equivalent alternatives to patients.

The pharmacy management tools we use lower costs. Thanks to pharmacy benefit managers like CVS Caremark, American consumers and plan sponsors will save \$654 billion from 2016 to 2025. Most importantly, when prescriptions are more affordable, patients are more likely to keep taking them – and that leads to healthier people and communities.



Studies have shown that **greater medication adherence for chronic disease** could save over **\$300 billion in unnecessary medical costs** each year and **save tens of thousands of lives.**

(Source: Thinking outside the pillbox, New England Healthcare Institute, August 2009.)

Today, more competition is needed to counter rising drug prices and there are several policies we can adapt to clear the path for more competition and more affordable drugs:

Increase Competition in the Marketplace

1. Speed the Food and Drug Administration's (FDA) approval of generic drugs.
2. Expedite FDA review for drugs with no competition.
3. Increase the availability of biosimilars.
4. Curb anti-competitive practices like "pay-for-delay" agreements that block generic drug competition.
5. Allow generic and biosimilar manufacturers to obtain samples of branded drugs to help facilitate competition.

Increase Competition in Medicare Part D

Increase Transparency and Support

The simple truth: Patients lose access when they can't afford their medications. By increasing competition, we can lower costs, increase access, and drive continued innovation.

[« Back](#)

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EXHIBIT 3

Medicare Part D – Single-Source Generics (SSGs)
Frequently Asked Questions
Internal Use Only. Not for Distribution.
March 2017

Background

Generic prescription drugs are typically the lowest-cost option when compared to brand-name prescription drugs. Clients promote the use of generics to help plan beneficiaries save money. Pricing for new single-source generic drugs has historically been quite high due to exclusivity.

Uncertainty in the timing of single-source generic launches can present planning and budgetary challenges for Med D plans. Generic launch dates can be unpredictable, making annual formulary planning difficult. Initially, pricing for single-source generics may be similar to the brand until other manufacturers enter the market and negotiated rebates can be adversely affected.

A single-source generic (SSG) strategy is a cost-containment strategy that may involve maintaining the brand drug in an existing tier or moving the brand drug to a lower tier and excluding the generic drug from the formulary.

- Placing the brand on a lower tier on the plan formulary can bring clients additional rebates which can lower their overall plan costs
- This will also produce savings for members through lower copays in the initial coverage level
- Once multi-source generics become available at a more competitive price, formulary coverage typically is updated to cover the generic drug

In 2016, we estimate that clients participating in the SSG program had average total drug cost savings that ranged from \$22.52 to \$272.85. Please note that client results will vary based on plan design, formulary status, demographic characteristics and other factors.

How the SSG Strategy Works

Once a generic is available, CVS Caremark® will apply one of two strategies, based on financial benefits to members:

- Do not include the SSG on the formulary; maintain the branded drug in the existing tier **OR**
- Do not include the SSG on the formulary; down tier the brand and reduce the member copay

Note: the typical period of exclusivity for a generic manufacturer is 180 days.

Important Updates to the SSG Strategy: Effective 1/1/18

The evaluation, analysis and implementation of an SSG strategy requires considerable resources to help ensure the approach is appropriate and successful for participating clients. The increasing complexity of this process is requiring additional resources and can no longer be offered to clients without a fee. Effective January 1, 2018, a \$15K per launch fee will continue to be applied for the SSG program.

- This program will now be available to **all** clients, provided criteria are met and the fee is paid
- Clients must opt into the entire program for the full year; they cannot join or leave mid-year or choose drug-by-drug participation. They may, however, disenroll for the following calendar year.
- Payment is due at year end and will be based on the number of launches per year

Please be aware, there are new eligibility criteria (see Q2 under Client Eligibility section) that must be met by clients in order to participate and clients must make a decision to participate by May 5, 2017 (for a 1/1/18 effective date). If we do not hear back by May 5, 2017, it will be assumed that the client will not participate for calendar year 2018.

**Medicare Part D – Single-Source Generics (SSGs)
Frequently Asked Questions
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GENERAL QUESTIONS

Q1: Why is there now a fee?

A1: CVS Caremark will begin charging a yearly fee for the administrative work that is required to implement this program. Many programs may be initially offered with no fee, but as the programs grow in adoption and complexity, additional resources are required to help ensure the approach is successful for all clients included.

Q2: What is the fee? How did we determine the fee? Will it stay the same each year?

A2: The annual fee will be based on the number of SSG launches in 2018. The charge per launch is \$15,000 per client regardless of size. We will re-evaluate the yearly fee each year. **NOTE:** Clients may not pick and choose drug launches to participate in. If they opt in for the year, they will participate in and pay for all launches in that year.

Q3: When and how is the fee paid?

A3: The fee is paid at the end of the year and is based on the number of launches during the year.

Q4: What happens if there are no drug launches in a given year?

A4: There will be no charge to the client if there are no launches in a given year.

Q5: When is the change effective? What if my client can't make a decision by 5/5/17?

A5: The change is effective 1/1/18. **Client decisions must be made by 5/5/17** in order to appropriately request proper Centers for Medicare & Medicaid Services (CMS) formulary submission identifications that are required for opt-in carriers. If we do not hear back from a client by May 5, 2017, it will be assumed that the client will not participate for calendar year 2018.

Q6: Who is affected by this change?

A6: All Medicare Part D health plan clients (those that opted in and opted out) are impacted. Current opt-in clients will have to pay a yearly fee to participate and must meet new strict criteria to continue opt-in status/participation in the program or be disenrolled from the program. Current opt-out clients may now choose to participate in 2018 if they meet the criteria and pay a yearly program fee.

Q7: Is this program only for Medicare Part D? What about commercial, employer group waiver plans (EGWPs), Medicaid or exchange business?

A7: This approach is for Medicare Part D plans only, as it is implemented only when the 50 percent manufacturer discount in the Medicare Part D coverage gap applies. It is not for commercial, Medicaid or exchange business, and cannot be applied to EGWPs due to complications with enhanced OHI (other health insurance) benefits and meeting the manufacturer rebate obligations. The approach also cannot be implemented with Medicare Part D clients that have their EGWP formulary imbedded in the same carrier as their health plan formulary.

Q8: Will all clients be required to pay the fee?

A8: Yes, ALL clients enrolling in the SSG program are required to pay the annual fee and must meet the criteria to participate.

Q9: Will you grandfather existing opt-in clients?

A9: No, we will not grandfather existing opt-in clients. Current opt-in clients will have to pay the annual fee to participate and must meet new strict criteria or be disenrolled from the program.

Medicare Part D – Single-Source Generics (SSGs)
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- Q10: Will this program be added to the client value playbook (CVP) for the sales team?**
A10: More information is forthcoming on this topic.
- Q11: When does my client have to decide to opt in and who should they contact?**
A11: Client decisions are due back by **May 5, 2017**. Account teams should contact Camille Bralts at Camille.Bralts@CVSCaremark.com with a final decision. Please provide the following 2017 information to Camille:
- Plan name
 - CMS contract #
 - Plan type (IND, EGWP, SNP, MMP)
 - Carrier
 - Account
 - Group
 - PBP
 - Formulary name
 - Opt-In/Opt-Out Status
- Q12: What drugs might launch in 2018?**
A12: Subject to change, we anticipate that Reyataz, Sustiva, Adcirca, Sensipar and Canasa may launch and be eligible for this program in 2018. The likelihood of participation is contingent on the financials working for members, the plan and CMS.
- Q13: Can my client pick which drug launches to participate in?**
A13: No, clients must opt into the entire program for the full year, they cannot join or leave mid-year or choose drug-by-drug participation. They may disenroll for the following calendar year.
- Q14: Will participation require a contract amendment or other legal document?**
A14: Yes. Please download and complete the **Contract Request Form** from Salesforce when the client informs the account team of its decision to implement the SSG solution: (a) Allow at least 30 days for the Completion Date of Request; (b) For the Reason of Request, indicate that you are seeking a contract addendum for the Medicare Part D Single Source Generic product offering; (c) Send the completed form to Legal's **Contract Request mailbox** at least 120 days ahead of the implementation date (thus allowing at least 90 days for internal teams to implement client requests.)
- Q15: What formularies are available for the SSG program in 2018?**
A15: The following formulary options are the **only** ones available with the SSG program:
- SSG 5T Generic Strategy Standard
 - SSG 5T Select
- Q16: My client is currently participating in the SSG for 2017, but will not be eligible for 2018. Can they continue to participate with existing SSG strategies that may roll over to 2018 (Copaxone, Exelon Patch as examples)?**
A16: No. A client currently opted in, but who no longer meets criteria for 2018, will be disenrolled from the SSG strategy effective 1/1/18. The client will not continue on existing roll-over SSG strategies in 2018.
- Q17: Will you charge clients for existing SSG strategies that are rolled over from 2017 to 2018?**

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Medicare Part D – Single-Source Generics (SSGs)
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A17: We will NOT charge clients (new or existing opt-ins) for the existing SSG strategies that roll over to 2018.

BIDS/BID ADVISOR

Q1: Will this impact my client's bid?

A1: It may impact your client's bid IF your client is currently participating in the SSG program but will opt out for 2018. The account team should communicate to their clients that the change in rebate may affect their bid and they should adjust accordingly.

Q2: Will this be incorporated into the Bid Advisor for 2018 formulary planning?

A2: Because of uncertainty in launches, bids should be done assuming the generic is in place.

CLIENT ELIGIBILITY

Q1: Is this program beneficial for small clients?

A1: We have found that this program's return on investment (ROI) may not be positive for clients with less than 50,000 eligible Med D lives.

Q2: What are the requirements?

A2: Please review the following eligibility criteria carefully. If you have any questions regarding your specific client, please contact Troy Wieck and Dominic Duke. You will find their contact information at [end of this document](#).

- CVS Caremark must provide both rebate management and claims adjudication
- SSG opt-in plans need their own CMS formulary submission;
 - All opt-in CAG must align to the SSG formulary submission
 - All CAG not adopting the SSG strategy must have a unique non-SSG formulary submission
- Clients must opt into the entire program for the full year; they cannot join or leave mid-year or choose drug-by-drug participation. They may disenroll for the following calendar year.
- Clients must adhere to the transition fill (TF) block policy for renewing members. Per the TF block logic of the SSG program, a renewing member with the equivalent brand drug in the renewing member history look-back period will not be eligible for a transition fill of the generic with the same formulation within the renewing member TF eligibility period which is typically the first 90 days of the calendar year. The pharmacy will be messaged to dispense the brand instead. The SSG strategy TF block logic applies to only renewing members and will not apply to new members, LTC emergency supply and LTC New Patient TF claims.
- Formulary Requirements:
 - 1, 2 and 3 tier formularies are not eligible
 - Custom formularies are not eligible
 - Formularies that primarily do not have brands and generics on all tiers are not eligible (Expanded, Expanded Performance, 2T MMP, 1T Standard, 4T Standard and 5T Standard)
- Special Needs Plans (SNPs) are not eligible. In addition, SSG cannot be implemented if a CMS formulary ID is shared with a SNP.
- EGWPs are not eligible. In addition, SSG cannot be implemented if a CMS formulary ID is shared with an EGWP.
- MMPs (also known as dual-demo project clients or Fully Integrated Duals Advantage program in NY) and managed Medicaid plans are not eligible.
- Clients that have previously opted-out may participate if they meet the criteria, and pay the annual fee

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Medicare Part D – Single-Source Generics (SSGs)
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- Clients that have dispense-as-written (DAW) 5 set to reject are excluded

Q3: Why can't EGWPs participate?

A3: Plan design complexity prevents us from implementing SSG for EGWPs:

Q4: Why are SNPs and MMPs excluded?

A4: A drug will be eligible for consideration in the SSG program if including the drug will, on average and in the aggregate, result in equal or lower cost to the plan and members versus use of the newly introduced single-source generic. This strategy is intended for use with Medicare Part D clients only, and is not applicable to dual-demo project clients (e.g., Managed Medicaid plans and the Fully Integrated Duals Advantage program in New York). All SNPs are also excluded as the benefit is defined as standard and the member is nearly always eligible for low-income subsidies.

Q5: Why is my client no longer eligible to participate?

A5: Clients become ineligible if they do not meet the new criteria. Refer to comprehensive list in [question 2](#).

Clients may become newly eligible in 2018 if criteria are now met. For example, a client that changes from a 1 tier formulary to a participating SSG formulary may become eligible for the program provided the other criteria are met and the annual fee is paid.

Q6: What if my client has a custom formulary?

Q6: Clients that have a custom formulary are excluded from participation.

Q7: How can I tell if my client is a good candidate? Who can help me determine if the ROI is worth the fee? What output will I receive to take to the client?

A7: Please contact Troy Wieck or Dominic Duke in actuarial services. Their [contact information](#) can be found at end of this document. Request should include client name, 2016 CMS contracts, carrier/account/group/PBP information, and exclusion information (SNPs, on 1 tier, etc.).

Analysis takes approximately 10 business days; the report will include list of drugs expected to launch as generics, 2016 Rx count and an estimated savings range.

Q8: How will the products process for my client that did not opt-in to the strategy?

A8: For clients that did not opt-in to the SSG Drug Strategy, the generic will be added to the appropriate tier and the brand will continue to process at the current formulary tier.

REPORTING

Q1: What type of reporting is available to show estimated results?

A1: We will provide the client with a range of estimated plan gross savings for SSG drugs prior to the decision to opt in.

CLINICAL

Q1: What if my client who adopted the strategy has generic dispensing rate guarantees?

A1: Contact your SAE to submit an Underwriting request to research the effect and revise the guarantee.

**Medicare Part D – Single-Source Generics (SSGs)
Frequently Asked Questions
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Q2: Has the National Pharmacy & Therapeutics (P&T) Committee approved these changes?

A2: We utilize the services of the independent National P&T Committee to review safe and clinically effective drug therapies in accordance with CMS requirements for Medicare Part D as related to P&T Committee regulations.

Our P&T Committee will review and approve our 2018 Medicare Part D formularies. The movement of a brand drug to a lower (i.e., more favorable) tier would be classified as a less restrictive change in availability of a medication on a Medicare Part D formulary. Less restrictive changes to Medicare Part D formularies would require a notification to our P&T Committee of the change to continue to remain compliant with CMS Medicare Part D regulations.

Q3: Is this change permissible in states that mandate generic dispensing?

A3: The Medicare Part D rules allow a plan to retain a brand on the Medicare Part D formulary with a generic copay and to exclude the newly released generic. While state pharmacy substitution laws are a pharmacy issue – and not a plan issue – the generic substitution laws would not pose a barrier to this strategy because such laws generally are based on economic advantage to the member as a result of receiving the generic.

Note: A few of the states with generic substitution laws have more restrictive requirements. Nonetheless, the intent of these stricter pharmacy substitution laws is that consumers of prescription drug products may realize cost savings by buying less expensive, safe drug products. This is consistent with the SSG strategy, and therefore these laws should not be problematic.

QUESTIONS

General Questions:

Camille Bralts: Camille.Bralts@CVSCaremark.com

Emily Ziegler: Emily.Ziegler@CVSCaremark.com

David Eason: David.Eason@CVSCaremark.com

Client Evaluation:

Troy Wieck at Troy.Wieck@CVSCaremark.com or Dominic Duke at

Dominic.Duke@CVSCaremark.com

EXHIBIT 4

**INTERNAL ONLY SLIDE:
REMOVE BEFORE USE**

Single-Source Generics: Implementation Restrictions

Please read the FAQs for the complete list of criteria

This presentation is intended for use with Medicare Part D clients only

- Not currently applicable to Dual Demo project clients (MMPs), EGWPs or SNPs
- Custom formularies are not eligible
- Clients that have DAW 5 set to reject are excluded
- Clients terminating their PBM contract in 2019 are ineligible
- Cannot be implemented with Medicare Part D clients that have their EGWP and/or SNP formulary embedded in the same carrier as their health plan formulary

The following formulary option is the only one available with the SSG program:

- 5T Select SSG

Questions regarding general information?

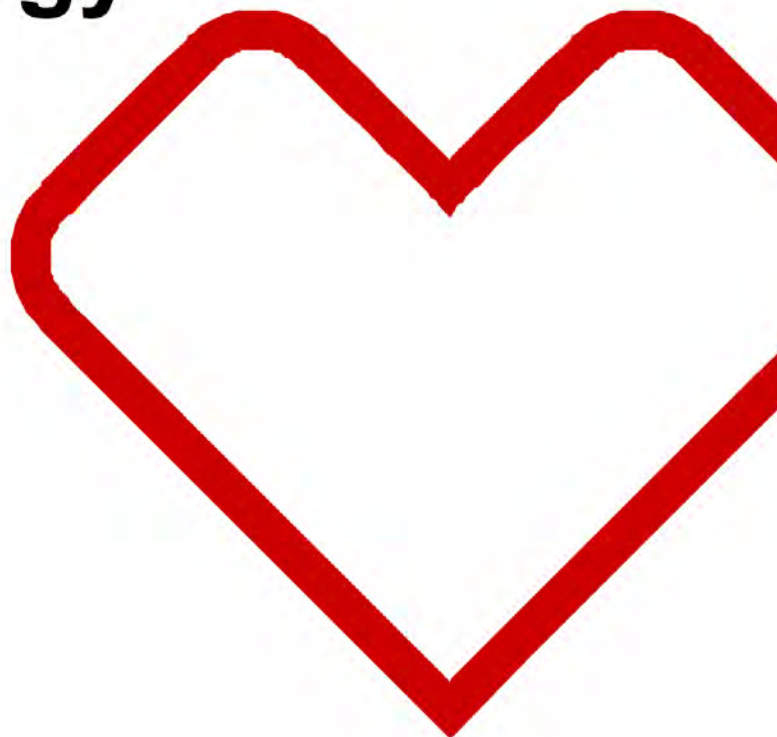
- Bethany Crotts at Bethany.Crotts@CVSHealth.com
- Caitlin Shorette at Caitlin.Shorette@CVSHealth.com

IMPORTANT: Please remove all speaker notes before sending to client

Medicare Part D Single-Source Generic Strategy

Speaker's Name

Date of Presentation





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Single-Source Generics Aren't Always the Most Cost-Effective Choice

- In most cases, generics cost less than branded prescription drugs
- Members and clients generally save when plan designs encourage generic use
- However, single source generics challenge this model

SINGLE-SOURCE GENERICS: A NEW CHALLENGE

- SSGs are new-to-market generics produced by a single manufacturer
- Historically, pricing for SSGs has been approximately the same or higher than branded drugs because of exclusivity

THE LAUNCH OF A SINGLE SOURCE GENERICS PRESENTS CHALLENGES FOR BOTH CLIENTS AND MEMBERS

Uncertainties Generic of Launches Present Planning Challenges for Medicare Part D Plans

Medicare Part D plans face planning and budgetary challenges due to uncertainties around generic launches

- Generic launch dates can be unpredictable, making annual formulary planning difficult
- Initial pricing for SSGs may be similar to the brand until other manufacturers enter the market
- Brands' net of discount may cost less than generics

Historical Generic Launches

	Expected Generic Launch	Actual Generic Launch
Copaxone	May 2014	Jun 2015
Nexium	May 2014	Oct 2015
Exelon Patch	Jan 2015	Sept 2015

This slide contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Health.

Source: CVS Pipeline and brand manufacturer information.

Off-Schedule Generic Launches Can Have a Negative Impact on Members and Plans

MEMBERS

- Immediately moving from a brand to a new generic may not reduce member cost share
 - SSG pricing may be similar to the brand
 - Generic manufacturers provide less gap assistance, which may result in added cost burden
 - Brand manufacturers pay a 75% rebate discount in 2019

PLANS

- Member use of SSGs leads to loss of brand rebates without necessarily reducing plan costs
- When generics launch off schedule, loss of rebates could affect submitted bids

CVS Caremark® Part D Services LLC can help Medicare Part D plans address generic launch uncertainties

Single-Source Generic Strategy Can Help Minimize Disruption, Maximize Savings

BENEFITS

- Helps minimize the negative impact of high-cost SSG launches
 - Mitigate member disruption (i.e., limited supply or possible cost differential)
 - Protect rebates in the budgeting process
 - Maximize prescription savings

PRESCRIPTION SAVINGS

- Based on review of your membership, participation in the SSG strategy would yield a per script savings of \$42.30 to \$123.25.

1. Client results will vary based on plan design, formulary status, and demographic characteristics, among other factors not listed.

2. Non-LICS members. Source: CVS Caremark Analytics, 2015.

Projections based on CVS Caremark data. Individual results will vary based on plan design, formulary status, demographic characteristics and other factors. Client-specific modeling available upon request. CVS Health uses and shares data as allowed by applicable law, our agreements and our information firewall.

Targeted Approach Ensures Success for Participating Clients

IMPLEMENTATION AND MANAGEMENT OF THE SSG STRATEGY

- Continuous surveillance and analysis of market events and pricing to determine when to cover the SSG
- Dedicated team to coordinate the implementation and management of SSG opportunities and launches
- Operational infrastructure to ensure all systems and processes align, including applicable regulations
- Criteria specifically designed to deliver improved return on investment for participating clients

Eligible clients can opt in or opt out on an annual basis.

Fee Structure for the SSG Strategy

- Clients will be charged \$15K for each new SSG drug launched into the strategy
- Payment for all launches is due at the end of 2020
- Detailed client analysis is available from Actuarial Services

HISTORICAL VIEW OF SSG LAUNCHES

	Number of Launches	Examples of Drugs Included
2015	3	<ul style="list-style-type: none"> • Copaxone 20mg • Exelon • Invega
2016	9	<ul style="list-style-type: none"> • Benicar/HCT • Zetia • Voltaren
2017	2	<ul style="list-style-type: none"> • Azilect • Copaxone 40mg
2018	4	<ul style="list-style-type: none"> • Istalol • Estrace • Welchol Tabs/Packets

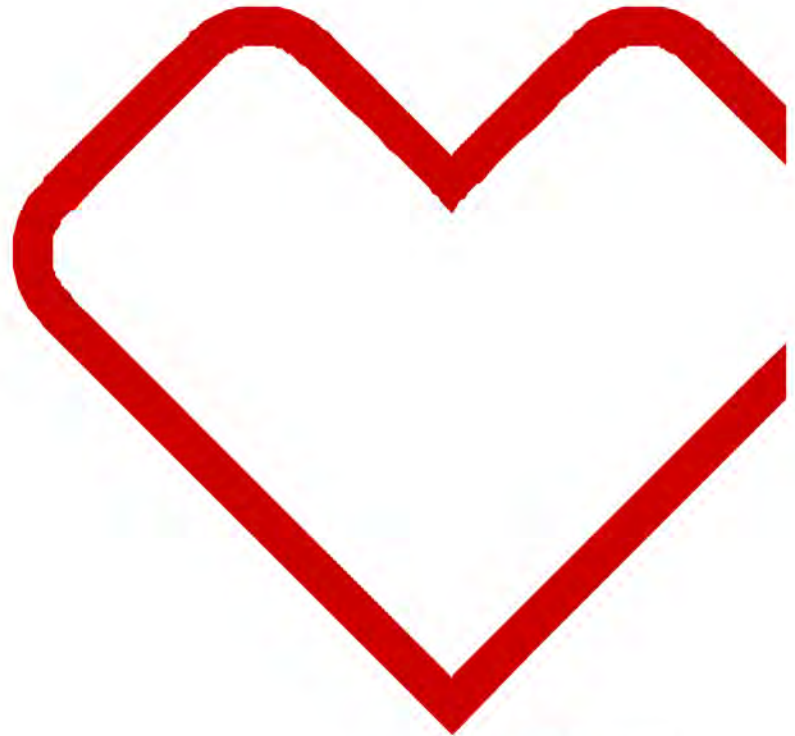
Potential SSG Launches

IMPLEMENTATION AND MANAGEMENT OF THE SSG STRATEGY

- Generic pipeline monitoring, coupled with detailed financial analysis, determines potential SSG opportunities
- To date, two new SSG have been launched in the strategy for 2019:
 - Butrans transdermal patch
 - Canasa rectal suppository
- An estimated 15-20 additional opportunities have been identified for 2019 and 2020

Eligible clients can opt in or opt out on an annual basis.

Thank You



INTERNAL USE ONLY.

Resources

Actuarial Analyses:

- Rebecca Justice Rebecca.Justice@CVSHealth.com
- Dominic Duke Dominic.Duke@CVSHealth.com

General Program Questions:

- Bethany Crotts Bethany.Crotts@CVSHealth.com
- Caitlin Shorette Caitlin.Shorette@CVSHealth.com



Rebate Related Questions:

- Your CSS representative

EXHIBIT 5

**INTERNAL ONLY SLIDE:
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Single-Source Generics: Implementation Restrictions

Please read the FAQs for the complete list of criteria

This presentation is intended for use with Medicare Part D clients only

- Not currently applicable to Dual Demo project clients (MMPs), EGWPs or SNPs
- Custom formularies are not eligible
- Clients that have DAW 5 set to reject are excluded
- Clients terminating their PBM contract in 2019 are ineligible
- Cannot be implemented with Medicare Part D clients that have their EGWP and/or SNP formulary embedded in the same carrier as their health plan formulary

The following formulary option is the only one available with the SSG program:

- 5T Select SSG

Questions regarding general information?

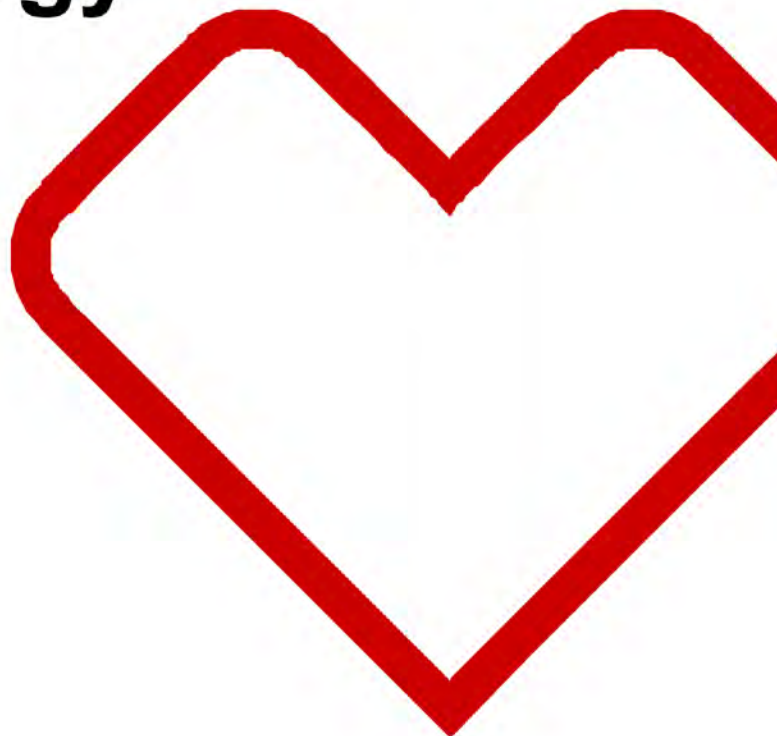
- Bethany Crofts at Bethany.Crofts@CVSHealth.com
- Caitlin Shorette at Caitlin.Shorette@CVSHealth.com

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Medicare Part D Single-Source Generic Strategy

Speaker's Name

Date of Presentation



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Single-Source Generics Aren't Always the Most Cost-Effective Choice

- In most cases, generics cost less than branded prescription drugs
- Members and clients generally save when plan designs encourage generic use
- However, single source generics challenge this model

SINGLE-SOURCE GENERICS: A NEW CHALLENGE

- Single source generics (SSGs) are new-to-market generics produced by a single manufacturer
- Historically, pricing for SSGs has been approximately the same as or higher than branded drugs due to exclusivity

THE LAUNCH OF A SINGLE SOURCE GENERICS PRESENTS CHALLENGES FOR BOTH CLIENTS AND MEMBERS

Uncertainties Generic of Launches Present Planning Challenges for Medicare Part D Plans

Medicare Part D plans face planning and budgetary challenges due to uncertainties around generic launches

- Generic launch dates can be unpredictable, making annual formulary planning difficult
- Initial pricing for SSGs may be similar to the brand until other manufacturers enter the market
- Brands' net of discount may cost less than generics

Historical Generic Launches

	Expected Generic Launch	Actual Generic Launch
Exelon Patch	Jan 2015	Sept 2015
Gleevec	July 2015	Feb 2016
Rapaflo	Mar 2017	Nov 2018
Canasa	June 2018	Dec 2018

This slide contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Health.

Source: CVS Pipeline and brand manufacturer information.

Off-Schedule Generic Launches Can Have a Negative Impact on Members and Plans

MEMBERS

- Immediately moving from a brand to a new generic may not reduce member cost share
 - SSG pricing may be similar to the brand
 - Generic manufacturers provide less gap assistance, which may result in added cost burden
 - Brand manufacturers pay a 70% rebate discount in 2019

PLANS

- Member use of SSGs leads to loss of brand rebates without necessarily reducing plan costs
- When generics launch off schedule, loss of rebates could affect submitted bids

CVS Caremark® Part D Services LLC can help Medicare Part D plans address generic launch uncertainties

Single-Source Generic Strategy Can Help Minimize Disruption, Maximize Savings

BENEFITS

- Helps minimize the negative impact of high-cost SSG launches
 - Mitigate member disruption (i.e., limited supply or possible cost differential)
 - Protect rebates in the budgeting process
 - Maximize prescription savings

PRESCRIPTION SAVINGS

- Based on review of your membership, participation in the SSG strategy would yield a per script savings of \$42.30 to \$123.25.

1. Client results will vary based on plan design, formulary status, and demographic characteristics, among other factors not listed.

2. Non-LICS members. Source: CVS Caremark Analytics, 2019.

Projections based on CVS Caremark data. Individual results will vary based on plan design, formulary status, demographic characteristics and other factors. Client-specific modeling available upon request. CVS Health uses and shares data as allowed by applicable law, our agreements and our information firewall.

Targeted Approach Ensures Success for Participating Clients

IMPLEMENTATION AND MANAGEMENT OF THE SSG STRATEGY

- Continuous surveillance and analysis of market events and pricing to determine when to cover the SSG
- Dedicated team to coordinate the implementation and management of SSG opportunities and launches
- Operational infrastructure to ensure all systems and processes align, including applicable regulations
- Criteria specifically designed to deliver improved return on investment for participating clients

Eligible clients can opt in or opt out on an annual basis

Fee Structure and SSG Pipeline

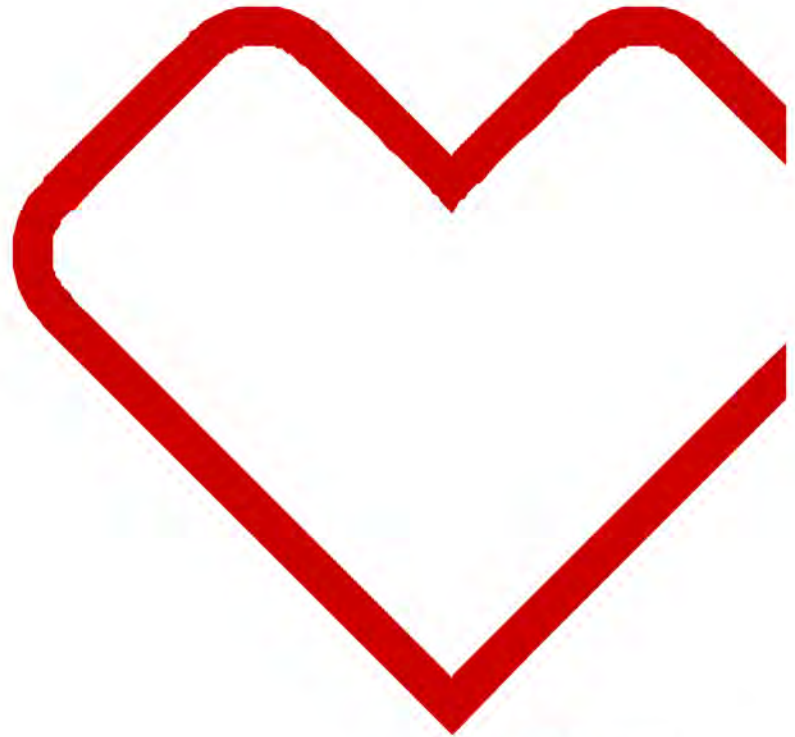
- Clients will be charged \$15K for each new SSG drug launched into the strategy
- Payment for all launches is due at the end of 2020
- Detailed client analysis is available from Actuarial Services
- Generic pipeline monitoring, coupled with detailed financial analysis, determines potential SSG opportunities

HISTORICAL VIEW OF SSG LAUNCHES

	Number of Launches	Examples of Drugs Included
2015	3	<ul style="list-style-type: none"> • Copaxone 20mg • Exelon • Invega
2016	9	<ul style="list-style-type: none"> • Benicar/HCT • Zetia • Voltaren
2017	2	<ul style="list-style-type: none"> • Azilect • Copaxone 40mg
2018	4	<ul style="list-style-type: none"> • Istalol • Estrace • Welchol Tabs and Packets

15-20 CURRENTLY MONITORED FOR POTENTIAL 2019 AND 2020 SSG OPPORTUNITIES

Thank You



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Resources

Actuarial Analyses:

- Rebecca Justice Rebecca.Justice@CVSHealth.com
- Dominic Duke Dominic.Duke@CVSHealth.com

General Program Questions:

- Bethany Crotts Bethany.Crotts@CVSHealth.com
- Caitlin Shorette Caitlin.Shorette@CVSHealth.com

Rebate Related Questions:

- Your CSS representative



EXHIBIT 6

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Medicare Part D Single-Source Generic Strategy

Investing in You

April 1, 2017

Part D PBM services are provided by
CVS Caremark Part D Services, L.L.C.



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Single-Source Generics Aren't Always the Most Cost-Effective Choice

- In most cases, generics cost less than brand prescription drugs
- Plan members and clients save when plan designs encourage use of generics
- However, SSGs challenge this model

SINGLE-SOURCE GENERICS: A NEW CHALLENGE

- SSGs are new-to-market generics produced by a single manufacturer
- Historically, pricing for SSGs has been approximately the same or higher than brand drugs because of exclusivity

The launch of a single-source generic presents challenges for both clients and plan members

SSG (Single-Source Generic).

Generic Launch Uncertainties Present Planning and Budgetary Challenges for Med D Plans

- Generic launch dates can be unpredictable, making annual formulary planning difficult
- Initial pricing for SSGs may be similar to the brand until other manufacturers enter the market
- Brands' net of rebate may cost less than generics

Copaxone	May 2014	Jun 2015
Nexium	May 2014	Oct 2015
Exelon Patch	Jan 2015	Sep 2015
Aggrenox	Jul 2015	Jul 2015
Zetia	Dec 2016	Dec 2016

This slide contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Health.
Source: CVS Pipeline and brand manufacturer information.

Off-Schedule Generic Launches Can Have a Negative Impact on Members and Plans

MEMBERS

- Immediately moving from a brand to a newly available generic may not reduce member cost share
 - SSG pricing may be similar to the brand
 - Generic manufacturers are not required to provide gap assistance, resulting in added cost burden
 - Brand manufacturers pay 50% of the cost directly to the member in the coverage gap at the point of sale

PLANS

- Member use of SSGs leads to forfeiture of negotiated rebates without reducing plan costs
- When generics launch off schedule, loss of rebates could affect submitted bids

CVS Caremark® Part D Services, L.L.C. can help Medicare Part D plans address generic launch uncertainties

SSG Strategy Can Help Minimize Disruption, Maximize Savings

BENEFITS

- Helps minimize the negative impact of high-cost SSG launches
 - Mitigates member disruption (i.e., limited supply or possible cost differential)
 - Protects rebates in the budgeting process
 - Maximizes prescription savings

HISTORICAL SAVINGS

Based on review of three health plan clients participating in the SSG program with five drug launches over a six-month period in 2016:

- \$160 average total drug cost saving per Rx¹

1. Client results will vary based on plan design, formulary status, demographic characteristics, and other factors not listed. Non-LICS members. Source: CVS Caremark Analytics, 2016. Projections based on CVS Caremark data. Client-specific modeling available upon request.

Current SSG Strategy

- Select best approach until additional competition comes to market:
 - Don't cover SSG on formulary; maintain brand drug in existing tier OR
 - Don't cover SSG on the formulary and "down tier" the brand, reducing the member copay
- Daily monitoring of market events and pricing helps determine when to cover the SSG
 - Generic manufacturer exclusivity is typically 6 months
- Initial systems established to implement and manage SSG launches
 - Formulary and mail service set up, pharmacy notification, client script development, PA updates for each launch

**Current strategy is a one-size-fits-all approach;
value was not consistent for all participating clients.**

PA (Prior Authorization).

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Refined Approach Helps Ensure Success for all Participating Clients

- Continued monitoring, analysis, implementation and management of SSG opportunities and launches
- **New** operational infrastructure helps ensure all systems and processes align, including applicable regulations
- **Refined criteria** to help deliver improved return on investment for participating clients
 - New formularies to support SSG programs will be selected by the client
- Benefit from previous SSG launches not subject to the new fee

Eligible clients can opt in or opt out on an annual basis.

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New Criteria Encourages Participation Only for Clients with Greatest Savings Opportunity

Foundational Background

- A drug will be eligible for consideration in the SSG program if including the drug will, on average and in the aggregate, result in equal or lower cost to the plan and members, versus use of the newly introduced SSG
- We will not grandfather existing clients into the program; they must meet new criteria and pay the annual fee

Basic Client Eligibility Criteria

- CVS Caremark must administer the client's claims adjudication and rebate programs
- Clients must meet formulary eligibility requirements
- Program is not configurable; clients may not pick and choose SSG launches
- Only clients with the following formularies are eligible: *SSG 5T Generic Strategy Standard* and *SSG 5T Select*

Clients that have previously opted out may participate if they meet criteria.

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Criteria Should be Carefully Reviewed to Determine Client Eligibility

INELIGIBLE CLIENTS/PLAN DESIGNS

- ✓ **Special Needs Plans (SNPs), EGWPs, MMPs and dual-demo clients** are not eligible
- ✓ Clients that have **DAW 5** set to reject are excluded
- ✓ Clients **terminating** their PBM contract in 2017 are ineligible

INELIGIBLE FORMULARIES

- ✓ All formularies are ineligible but for **SSG 5T Generic Strategy Standard and SSG 5T Select**

Clients with less than 50,000 eligible Medicare Part D lives should be evaluated by Actuarial Services prior to presentation

EGWP (Employer Group Waiver Plan), MMP (Medicare-Medicaid Plan), DAW (Dispense at Written), PBM (Prescription Benefit Management).

Fee Structure for Refined SSG Program

- Clients will be charged \$15K for each SSG drug launched
- Payment, for all launches, is due at the end of 2018
- Fee will not apply for existing SSG strategies that carry over from 2017 to 2018; only for new launches in 2018
- 2018 projected product savings ranges are available from Actuary

Five anticipated launches in 2018:¹

- Reyataz
- Sustiva
- Adcirca
- Sensipar
- Canasa

Clients must opt in to participate and select a 2018 SSG formulary offering by May 5, 2017

1. Drugs that launch are subject to change and are based on FDA approval. Drugs expected to launch in 2017 may be delayed and increase the number of launches in 2018. This slide contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Health. Source: CVS Pipeline and brand manufacturer information.

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Rationale for Fee-Based SSG Management

- The evaluation, analysis, implementation and maintenance of a SSG strategy is resource intensive
- Increasing complexity of the process is requiring additional resources and can no longer be offered to clients at no cost as part of the core services
- The fee is to cover the administrative work that is required to implement this program

INTERNAL USE ONLY.**Key Dates to Remember**

Date	Milestone
3/23/17	Client Webinar — 2018 final formulary strategy, Bid Advisor, financial impact to clients
3/31/17	Preliminary formulary kits (2017) to clients (will not include SSG)
~4/1/17	Actuarial Services provides valuation for clients based on C/A/G information received
4/10/17	2 initial 2018 formulary kits will be prepared: Standard Template: Sent to clients who are not eligible for SSG Standard Template + SSG Template: Sent to existing SSG clients
April 2017	CAs/AMs/SAEs discuss with clients
4/26/17-4/28/17	Client Forum
5/5/17	Client decision due for SSG participation
Week of 5/8/17	Meeting with internal team (MPUFFS/FA, Med D Advancement) to review client selections

CAG (Carrier/Account/Group).

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Action Required for Account Team

- Review criteria for all ***clients currently participating*** to determine continued eligibility AND for ***clients who opted out who may now be eligible***
 - For eligible clients, request value analysis from:
Troy Wieck at Troy.Wieck@CVSCaremark.com or
Dominic Duke at Dominic.Duke@CVSCaremark.com
- Client decision and 2018 formulary selection are ***required by May 5, 2017***
 - Submit client name, CMS contracts, carrier/account/group/PBP information, formulary choice and opt-in/opt-out status to Camille Bralts
- In absence of a specific client decision, the client will be opted out for 2018

CMS (Centers for Medicare & Medicaid Services).

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Resources

Actuarial Analyses:

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- Dominic Duke Dominic.Duke@CVSCaremark.com

General Program Questions:

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- Emily Ziegler Emily.Ziegler@CVSCaremark.com
- David Eason David.Eason@CVSCaremark.com

Rebate Related Questions:

- Your CSS representative



EXHIBIT 7

**INTERNAL ONLY SLIDE:
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Single-Source Generics: Implementation Restrictions

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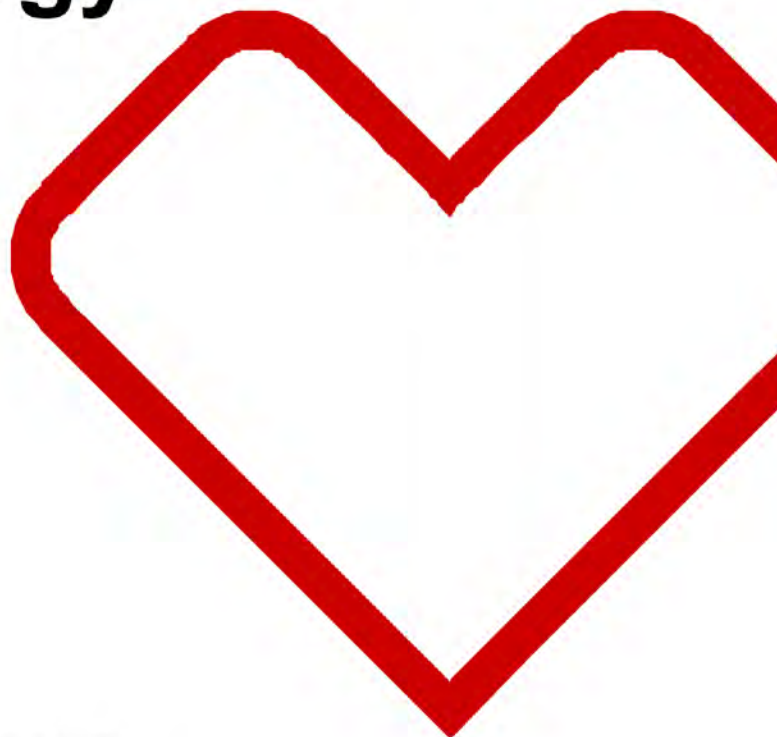
- Bethany Crotts at Bethany.Crotts@CVSHealth.com
- Caitlin Shorette at Caitlin.Shorette@CVSHealth.com

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Medicare Part D Single-Source Generic Strategy

Speaker's Name

Date of Presentation



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PRESCRIPTION SAVINGS

- Based on review of your membership, participation in the SSG strategy would yield a per prescription savings of \$42.30 to \$123.25.

1. Client results will vary based on plan design, formulary status, and demographic characteristics, among other factors not listed.

2. Non-low income subsidy (LIS) members. Source: CVS Caremark Analytics, 2019.

Projections based on CVS Caremark data. Individual results will vary based on plan design, formulary status, demographic characteristics and other factors. Client-specific modeling available upon request. CVS Health uses and shares data as allowed by applicable law, our agreements and our information firewall.

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Targeted Approach Helps Ensure Success for Participating Clients

IMPLEMENTATION AND MANAGEMENT OF THE SSG STRATEGY

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Fee Structure and SSG Pipeline

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- Generic pipeline monitoring, coupled with detailed financial analysis, determines potential SSG opportunities

HISTORICAL VIEW OF SSG LAUNCHES

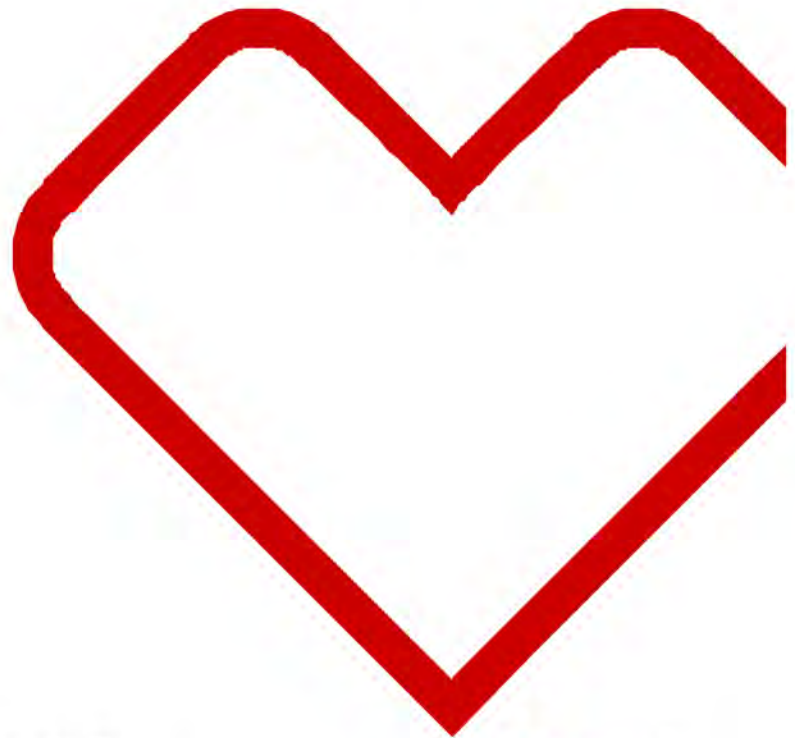
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2018	4	<ul style="list-style-type: none"> • Istalol • Estrace • Welchol Tabs and Packets

Currently monitoring 15 to 20 drugs for inclusion in the SSG strategy in 2019 and 2020

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Resources

Actuarial Analyses:

- Rebecca Justice Rebecca.Justice@CVSHealth.com
- Dominic Duke Dominic.Duke@CVSHealth.com

General Program Questions:

- Bethany Crotts Bethany.Crotts@CVSHealth.com
- Caitlin Shorette Caitlin.Shorette@CVSHealth.com



Rebate-Related Questions:

- Your CSS representative

CSS (Client Support Services).

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EXHIBIT 8



**Health Plan Client Strategy and FAQs
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Background

CANASA® rectal suppository was launched to market as a generic on December 15, 2018. Pricing is anticipated to be high for generic CANASA rectal suppository (mesalamine rectal suppository) until multisource generics become available.

CANASA Rectal Suppository Strategy

- Keep CANASA rectal suppository brand products on the existing Non-Preferred Brand Tier, Tier 4, effective February 22, 2019.
- Do not include mesalamine rectal suppository on the formulary until it becomes multi-sourced and its cost declines. At this time, we believe that the multisource launch will be at least 6 to 18 months after U.S. Food and Drug Administration (FDA) approval.
- At launch, single source generics (SSG) tend to be priced close to the brand. However, maintaining the rebate on the brand makes the net cost of the brand lower for the client and gives the member the additional discount when in the Coverage Gap Stage of their benefit.

Key Dates

- February 22, 2019: CANASA rectal suppository is kept on existing Non-Preferred Brand Tier, Tier 4. Generic mesalamine rectal suppository is blocked.

Clinical Advisor (CA) and Strategic Account Executive (SAE) Action Required

- Review this talk track. Be prepared to discuss the SSG program with your client enrolled in the program so you can ensure a successful implementation.
- **SAE action required**: Send your enrolled client the notification letter.
- If you have questions on the overall strategy, please read the General SSG Strategy Information section below.

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**Health Plan Client Strategy and FAQs
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Frequently Asked Questions

Q1: What if my client wants to opt out of the SSG strategy for this particular medication?

A1: Conditions for enrollment in the 2019 SSG strategy include an agreement to implement all of the recommended SSG drug strategies. Clients who have enrolled in SSG cannot opt out until January 1, 2020.

Q2: How will the products process for my client that did not opt into the strategy?

A2: For clients who did not opt into the SSG strategy, the generic mesalamine rectal suppository will be added to the formulary and brand CANASA rectal suppository will continue to process at the current formulary tier.

Q3: What if my client adopted the strategy and has generic dispensing rate guarantees?

A3: Your SAE should submit an Underwriting request to research the effect and revise the guarantee.

Q4: Has the National Pharmacy & Therapeutics (P&T) Committee approved these changes?

A4: We utilize the services of an independent National P&T Committee to review safe and clinically effective drug therapies in accordance with the Centers for Medicare & Medicaid Services (CMS) requirements for Medicare Part D. Our P&T Committee has reviewed and approved all of our 2019 Medicare Part D formularies that currently include CANASA rectal suppository.

Q5: Is this change permissible in states that mandate generic dispensing?

A5: The Medicare Part D rules allow a plan to retain a brand on the Medicare Part D formulary with a generic copay and to exclude the newly released generic. While state pharmacy substitution laws are a pharmacy issue – and not a plan issue – the generic substitution laws would not pose a barrier to this strategy because such laws generally are based on economic advantage to the member as a result of receiving the generic.

Note: A few of the states with generic substitution laws have more restrictive requirements. Nonetheless, the intent of these stricter pharmacy substitution laws is that consumers of prescription drug products may realize cost savings by buying less expensive, safe drug products. This is consistent with the SSG strategy, and therefore these laws should not be problematic.

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**Health Plan Client Strategy and FAQs
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Q6: How will this strategy work for members within the Coverage Gap Stage of their benefit?

A6: In general, the following applies to members within the Coverage Gap Stage:

- Members taking a generic may pay more in the Coverage Gap Stage for that generic product. This is dependent on New Drug Application (NDA) and Abbreviated New Drug Application (ANDA) status. In 2019:
 - NDA: Member would receive a 75 percent cost share discount in the Coverage Gap Stage.
 - ANDA: Member would receive a 63 percent cost share discount in the Coverage Gap Stage.
- Discussion point for clients: Beneficiaries may not hit the Coverage Gap Stage until mid-year, after the generic is available at a lower cost.

Q7: What process was followed to complete the analysis for each client?

A7: The client-specific savings analysis was calculated by looking at the plan design information provided by the account team, the cost share based upon member coverage stage, the average wholesale price (AWP) of both the brand and the generic, and the timing of the generic's launch within the plan year. If you have additional questions, please reach out to [Rebecca Justice](#).

Q8: Will CANASA rectal suppository be moved to a higher tier or removed from the formulary when generic mesalamine rectal suppository is added?

A8: CANASA rectal suppository will remain on the Non-Preferred Brand Tier, Tier 4 for 2019.

Q9: Is this program only for Medicare Part D? What about commercial, employer group waiver plans (EGWP), Medicaid, and exchange business?

A9: This approach is only implemented for Medicare Part D plans when the 75 percent manufacturer discount in the Medicare Part D Coverage Gap Stage applies. It is not for commercial, Medicaid or exchange business, and it cannot be applied to EGWPs due to complications with enhanced other health insurance benefits and meeting the manufacturer rebate obligations. This approach also cannot be implemented with Medicare Part D clients who have their EGWP formulary embedded in the same carrier as their health plan formulary.

Q10: How will we implement this initiative?

A10: We have assembled a large cross-functional team to make sure the implementation of this initiative is as smooth as possible. Sales leadership, benefits coding, mail service management, mail service plan coding, pharmacy network management, Medical Affairs, Clinical Operations, Customer Care, Trade and Medicare Part D management are all participating and setting direction.

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**Health Plan Client Strategy and FAQs
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Q11: If a strategy is still effective for your client in 2020, what happens for new members when they join the plan effective January 1, 2020?

A11: Members new to the plan will be granted a transition fill of the generic. They will be required to move to the brand at the next fill if applicable.

Q12: Will the generic process via transition fill as a non-formulary drug for Medicare Part D plans?

A12: Transition fills are available to:

- All newly enrolled beneficiaries
- All beneficiaries switching from one plan to another or change in their level of care from one treatment setting to another
- All beneficiaries aging into Medicare Part D (i.e., 64 years old turning 65 years old)
- All beneficiaries relocating into a Medicare Part D service area
- Auto-enrolled Medicare Part D/Medicaid full-benefit, dual-eligible beneficiaries
- Long-term care beneficiaries in need of an emergency supply

Note: Beneficiaries might pay more if they received a transition fill for the generic version.

General SSG Strategy Information

- Once a generic is available, CVS Caremark® will apply one of two strategies if generally financially beneficial to members:
 - Do not cover the SSG on the formulary. Maintain the branded drug in the existing tier, or
 - Do not include the SSG in the formulary. "Down-tier" the brand and reduce the member copay.
- Account teams will be notified once a strategy is determined to launch.
- The typical period of exclusivity for a generic manufacturer is 180 days.
- We monitor daily market events and pricing to determine when beginning coverage of the SSG is appropriate.

Talking Points/Internal Use Only documents are for verbal communication only and should not be shared in part or entirety in writing with clients, consultants or any other external audience. The contents should *not* be cut and pasted into any written communication or email. Please initiate requests for approval of written responses through Salesforce. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.
106-44442B 122717



**Health Plan Client Strategy and FAQs
FOR INTERNAL USE ONLY. NOT FOR DISTRIBUTION.**

SSG Strategy Criteria

- New clients can opt into the SSG strategy to address future generic launch uncertainties, provided they opt into the comprehensive strategy (i.e., clients cannot pick and choose).
- We analyze each product opportunity to help ensure the strategy meets necessary rebate requirements and member utilization threshold.
- A product will be eligible for consideration for the SSG program if such product's participation in the SSG program will, on average and in the aggregate, result in equal or lower cost to the plan and members versus use of the newly introduced SSG.
- Plan design complexity prohibits us from implementing EGWPs.

Talking Points/Internal Use Only documents are for verbal communication only and should not be shared in part or entirety in writing with clients, consultants or any other external audience. The contents should *not* be cut and pasted into any written communication or email. Please initiate requests for approval of written responses through Salesforce. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.
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EXHIBIT 9

Peoplesafe

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CAREMARK **PeopleSafe®** Close

Eligibility Maintenance **Participant Inquiry** Resolution Manager Medicare Inquiry View Opportunities Tools: -- Select A Tool --

Client: [REDACTED] **System:** RXCLAIM **Gndr:** F **Relationship:** MEMBER **Born:** 1943 **Effective:** 01-01-2014 **Expiration:** 12-31-2039

External ID: [REDACTED] **Name:** [REDACTED]

[Main Screen](#) [Financial Details](#) [View Activity](#) [Prescription History](#) [Test Claims](#) [Plan Benefit Overview](#) [Account Balance](#) [Explanation of Benefits](#) [Transaction History](#) [Communication History](#) [Caremark.com](#)

[Pharmacy Network](#) [Retail Transactions](#) [Plan Summary](#) [FSA/HSA/HRA History](#) [Coordination of Benefits](#) [Order Placement](#) [Adjustments](#) [Client Managed G & A](#) [View Triggers](#)

Prescription for: [REDACTED] **MEMBER** **Delivery System:** POINT OF SALE **Dispense As Written:** 0 - NO DAW
Prescription Number: [REDACTED] [Go to Reimbursement...](#) **Pharmacy NPI:** [REDACTED] **Drug Price Type:** AVERAGE WHOLESALE PRICE
Drug NDC: 68546032512 **Pharmacy NCPDP:** [REDACTED] **Drug Price Source:** MEDISPAN
Drug Name: [COPAXONE](#) **Pharmacy Name:** [REDACTED] **Client Claim Price Type:** [REDACTED] **Pharmacy Claim Price Type:** [REDACTED]

Participant Pay Participant Copay: 1901.46 Initial Copay: 1380.27 Gap Copay: 521.19 Catastrophic Copay: 0.00 Network Penalty: 0.00 Deductible: 343.69 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 2245.15	Client Pay Usual and Customary: 10497.60 Cost Submitted: 5876.66 Cost Allowed: 5876.66 Other Payer Recognized: 0.00 Dispensing Fee: 0.50 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 3634.01	Pharmacy Pay: Usual and Customary: 5878.66 Cost Allowed: 5878.66 Other Payer Recognized: 0.00 Dispensing Fee: 0.50 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 3634.01
---	--	--

Health Reimbursement Account:
 Benefits: 0.00
 Member Access Fee: 0.00
 Amount Used: 0.00
 HRA Remaining Balance: 0.00

Med D Financials:
 LICCS Paid by Plan: 0.00
 SPAP/Integrator Paid Amt: 0.00
 Reported Gap Discount: 1459.35
 Deductible Gross Cost: 343.69
 Deductible Plan Pay: 0.00
 Initial Gross Cost: 3450.69
 Initial Plan Pay: 2070.42
 Gap Gross Cost: 2084.78
 Gap Plan Pay: 1563.59
 Catastrophic Gross Cost: 0.00
 Catastrophic Plan Pay: 0.00

Miscellaneous
 Applied To Out of Pocket: 0.00
 Applied To TROOP: 0.00
 Applied To OOPM/MOOP: 0.00
 Paid by Other Insurance: 0.00
 Alternate Amount Paid: 0.00
 Previous Amount Paid: 0.00
 In Network Accumulation: 0.00
 Out of Network Accumulation: 0.00

[View Settlement Codes](#) [View Comments](#) [Back](#)

Pharmacy Reimbursement

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

Reversal

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

[View Reimbursements](#)

Recipient

Name:
 Alternate Name:
 Address:
 City:
 State:
 Zip:

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EXHIBIT 10

Peoplesafe

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CAREMARK **PeopleSafe®** Close

Eligibility Maintenance **Participant Inquiry** Resolution Manager Medicare D Inquiry View Opportunities Tools: -- Select A Tool --

Client: **SIL VERSCRIPT-INDIV-ENROLL** System: **RXCLAIM**

External ID: **[REDACTED]** Name: **[REDACTED]** Gender: **M** Relationship: **MEMBER** Birth: **[REDACTED] 1953** Effective: **01-01-2019** Expiration: **12-31-2039**

Main Screen Financial Details **View Activity** Prescription History Test Claims Plan Benefit Override Account Balance Explanation of Benefits Transaction History Communication History **Caremark.com**

Pharmacy Network Retail Transaction Plan Summary FSA/HSA/HRA History Coordination of Benefits Order Placement Adjustments Client Managed (G & A) **View Triggers**

Prescription for: **[REDACTED] MEMBER** Delivery System: **MAIL ORDER** Dispense As Written: **0 - NO DAW**

Prescription Number: **[REDACTED]** Pharmacy NPI: **[REDACTED]** Drug Price Type: **AVERAGE WHOLESALE PRICE**

Drug NDC: **58488013001** Pharmacy NCPDP: **[REDACTED]** Drug Price Source: **MEDISPAN**

Drug Name: **RENVELA** Pharmacy Name: **CAREMARK PRESCRIPTION SRVCS WEB** Client Claim Price Type: **[REDACTED]**

Pharmacy Claim Price Type: **[REDACTED]**

Participant Pay Participant Copy: 291.09 Initial Copay: 87.50 Gap Copay: 203.59 Catastrophic Copay: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 291.09	Client Pay Usual and Customary: Cost Submitted: 5714.99 Cost Allowed: 4581.17 Other Payer Recognized: 0.00 Dispensing Fee: 0.00 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 4290.08	Pharmacy Pay: Usual and Customary: Cost Allowed: 4581.17 Other Payer Recognized: 0.00 Dispensing Fee: 0.00 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 4290.08
---	--	---

Health Reimbursement Account:
 Benefits: 0.00
 Member Access Fee: 0.00
 Amount Used: 0.00
 HRA Remaining Balance: 0.00

Med D Financials:
 LICIS Paid by Plan: 0.00
 SPAP/Integrator Paid Amt: 0.00
 Reported Gap Discount: 570.07
 Deductible Gross Cost: 0.00
 Deductible Plan Pay: 0.00
 Initial Gross Cost: 3766.79
 Initial Plan Pay: 3679.29
 Gap Gross Cost: 814.38
 Gap Plan Pay: 610.79
 Catastrophic Gross Cost: 0.00
 Catastrophic Plan Pay: 0.00

Miscellaneous
 Applied To Out of Pocket: 0.00
 Applied To TROOP: 0.00
 Applied To OOPM/MOOP: 0.00
 Paid by Other Insurance: 0.00
 Alternate Amount Paid: 0.00
 Previous Amount Paid: 0.00
 In Network Accumulation: 0.00
 Out of Network Accumulation: 0.00

View Settlement Codes View Comments Back

EXHIBIT 11

Peoplesafe

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CAREMARK **PeopleSafe®** Close

Eligibility Maintenance ☐ Participant Inquiry ☐ Resolution Manager ☐ Medicare Inquiry ☐ View Opportunities Tools: -- Select A Tool --

Client: [REDACTED] - SILVERSCRIPT-INDIV-ENROLL System: RXCLAIM

External ID: [REDACTED] Name: [REDACTED] Gndr: F Relationship: MEMBER Born: [REDACTED] Effective: 01-01-2020 Expiration: 12-31-2039

[Main Screen](#) [Financial Details](#) [View Activity](#) [Prescription History](#) [Test Claims](#) [Plan Benefit Override](#) [Account Balance](#) [Explanation of Benefits](#) [Transaction History](#) [Communication History](#) [Caremark.com](#)

[Pharmacy Network](#) [Retail Transaction](#) [Plan Summary](#) [FSA/HSA/HRA History](#) [Coordination of Benefits](#) [Order Placement](#) [Adjustments](#) [Client Managed G & A](#) [View Triggers](#)

Prescription for: [REDACTED] MEMBER Delivery System: POINT OF SALE
 Prescription Number: [REDACTED] [Go to Reimbursement...](#) Pharmacy NPI: [REDACTED] Dispense As Written: 1 - PHYSICIAN DAW
 Drug NDC: 12496120803 Pharmacy NCPDP: [REDACTED] Drug Price Type: AVERAGE WHOLESALE PRICE
 Drug Name: SUBOXONE Pharmacy Name: CVS PHARMACY [REDACTED] Drug Price Source: MEDISPAN
 Client Claim Price Type: Pharmacy Claim Price Type:

Participant Pay Participant Copay: 1.77 Initial Copay: 91.91 Gap Copay: 0.00 Catastrophic Copay: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 1.77	Client Pay Usual and Customary: 287.46 Cost Submitted: 287.46 Cost Allowed: 241.47 Other Payer Recognized: 0.00 Dispensing Fee: 0.40 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 240.10	Pharmacy Pay: Usual and Customary: 241.47 Cost Allowed: 241.47 Other Payer Recognized: 0.00 Dispensing Fee: 0.40 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 240.10
--	--	--

Health Reimbursement Account: Benefits: 0.00 Member Access Fee: 0.00 Amount Used: 0.00 HRA Remaining Balance: 0.00	Miscellaneous Applied To Out of Pocket: 0.00 Applied To TROOP: 0.00 Applied To OOPM/MOOP: 0.00 Paid by Other Insurance: 0.00 Alternate Amount Paid: 0.00 Previous Amount Paid: 0.00 In Network Accumulation: 0.00 Out of Network Accumulation: 0.00
---	--

Med D Financials: LICs Paid by Plan: 90.14 SPAP/Integrator Paid Amt: 0.00 Reported Gap Discount: 0.00 Deductible Gross Cost: 0.00 Deductible Plan Pay: 0.00 Initial Gross Cost: 241.87 Initial Plan Pay: 149.96 Gap Gross Cost: 0.00 Gap Plan Pay: 0.00 Catastrophic Gross Cost: 0.00 Catastrophic Plan Pay: 0.00	View Settlement Codes View Comments Back
---	--

Pharmacy Reimbursement

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

Reversal

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

[View Reimbursements](#)

Recipient

Name:
 Alternate Name:
 Address:
 City:
 State:
 Zip:

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EXHIBIT 12

Peoplesafe

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CAREMARK **PeopleSafe®** Close

Eligibility Maintenance **N** Participant Inquiry **N** Resolution Manager **N** Medicare D Inquiry **N** View Opportunities Tools: -- Select A Tool --

Client: **SILVERSCRIPT-INDIV-ENROLL** System: **RXCLAIM**

External ID: **[REDACTED]** Name: **[REDACTED]** Gndr: **F** Relationship: **MEMBER** Born: **[REDACTED] 1930** Effective: **04-01-2018** Expiration: **12-31-2039**

Navigation: [Main Screen](#) [Financial Details](#) [View Activity](#) [Prescription History](#) [Test Claims](#) [Plan Benefit Overview](#) [Account Balance](#) [Explanation of Benefits](#) [Transaction History](#) [Communication History](#) [Caremark.com](#)

Pharmacy Network [Retail Transaction](#) [Plan Summary](#) [FSA/HSA/HRA History](#) [Coordination of Benefits](#) [Order Placement](#) [Adjustments](#) [Client Managed \(G & A\)](#) [View Triggers](#)

Prescription for: **[REDACTED] MEMBER** Delivery System: **POINT OF SALE**

Prescription Number: **[REDACTED]** [Go to Reimbursement...](#) Pharmacy NPI: **[REDACTED]** Dispense As Written: **[REDACTED]** Drug Price Type: **[REDACTED]** 9 - PLAN REQ BRAND AVERAGE WHOLESALE PRICE MEDISPAN

Drug NDC: **23590118** Pharmacy NCPDP: **[REDACTED]** Drug Price Source: **[REDACTED]**

Drug Name: **ASAGOL HD** Pharmacy Name: **[REDACTED]** Pharmacy Claim Price Type: **[REDACTED]**

Participant Pay	Client Pay	Pharmacy Pay:
Participant Copay: 95.25	Usual and Customary: 225.66	Usual and Customary: 190.01
Initial Copay: 95.25	Cost Submitted: 225.66	Cost Allowed: 190.01
Gap Copay: 0.00	Cost Allowed: 190.01	Other Payer Recognized: 0.00
Catastrophic Copay: 0.00	Other Payer Recognized: 0.00	Dispensing Fee: 0.50
Network Penalty: 0.00	Dispensing Fee: 0.50	Level Of Effort Fee: 0.00
Deductible: 0.00	Level Of Effort Fee: 0.00	Administration Fee: 0.00
MAC / DAW Penalty: 0.00	Administration Fee: 0.00	Performance / Service Fee: 0.00
Non Formulary Penalty: 0.00	Performance / Service Fee: 0.00	Sales Tax: 0.00
After MAB: 0.00	Sales Tax: 0.00	PDP Service Fee: 0.00
- FSA Contribution Amount: 0.00	PRX Fee Amount: 0.00	Other Amount Paid: 0.00
- HRA Contribution Amount: 0.00	Client Billed Cost: 0.00	
+ COB Non Covered Amt: 0.00		
=====		
Participant Cost: 95.25	Total Client Cost: 95.26	Total Pharmacy Reimbursement: 95.26

Health Reimbursement Account:	Miscellaneous
Benefits: 0.00	Applied To Out of Pocket: 0.00
Member Access Fee: 0.00	Applied To TROOP: 0.00
Amount Used: 0.00	Applied To OOPM/MOOP: 0.00
HRA Remaining Balance: 0.00	Paid by Other Insurance: 0.00
	Alternate Amount Paid: 0.00
	Previous Amount Paid: 0.00
	In Network Accumulation: 0.00
	Out of Network Accumulation: 0.00

Med D Financials:	
LICS Paid by Plan: 0.00	
SPAP/Integrator Paid Amt: 0.00	
Reported Gap Discount: 0.00	
Deductible Gross Cost: 0.00	
Deductible Plan Pay: 0.00	
Initial Gross Cost: 190.51	
Initial Plan Pay: 95.25	
Gap Gross Cost: 0.00	
Gap Plan Pay: 0.00	
Catastrophic Gross Cost: 0.00	
Catastrophic Plan Pay: 0.00	

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Pharmacy Reimbursement

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

Reversal

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

[View Reimbursements](#)

Recipient

Name:
 Alternate Name:
 Address:
 City:
 State:
 Zip:

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EXHIBIT 13

Peoplesafe

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CAREMARK		Peoplesafe®		Close	
Eligibility Maintenance	Participant Inquiry	Resolution Manager	Medicare Inquiry	View Opportunities	Tools: -- Select A Tool --
Client: SILVERSCRIPT-INDIV-ENROLL System: RXCLAIM External ID: Name: Gndr: M Relationship: MEMBER Born: 1947 Effective: 04-01-2018 Expiration: 12-31-2039					
Main Screen Financial Details View Activity Prescription History Test Claims Plan Benefit Overview Account Balance Explanation of Benefits Transaction History Communication History Carmark.com					
Pharmacy Network: Retail Transaction: Plan Summary: FSA/HSA/HRA History: Coordination of Benefits: Order Placement: Adjustments: Client Managed (G & A): View Triggers					
Prescription for: MEMBER Delivery System: POINT OF SALE Dispense As Written: 9 - PLAN REQ BRAND Prescription Number: Go to Reimbursement... Pharmacy NPI: Drug Price Type: AVERAGE WHOLESALE PRICE					
Drug NDC: 2420600403 Pharmacy NCPDP: Drug Price Source: MEDISPAN Drug Name: ISTALCY Pharmacy Name: CVS PHARMACY Client Claim Price Type: Pharmacy Claim Price Type:					
Participant Pay Participant Copay: 129.00 Initial Copay: 129.00 Gap Copay: 0.00 Catastrophic Copay: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 =====		Client Pay Usual and Customary: 1241.31 Cost Submitted: 1241.31 Cost Allowed: 1042.70 Other Payer Recognized: 0.00 Dispensing Fee: 0.40 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 914.10		Pharmacy Pay: Usual and Customary: 1042.70 Cost Allowed: 1042.70 Other Payer Recognized: 0.00 Dispensing Fee: 0.40 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 914.10	
Participant Cost: 129.00					
Health Reimbursement Account: Benefits: 0.00 Member Access Fee: 0.00 Amount Used: 0.00 HRA Remaining Balance: 0.00		Miscellaneous Applied To Out of Pocket: 0.00 Applied To TROOP: 0.00 Applied To OOPM/MOOP: 0.00 Paid by Other Insurance: 0.00 Alternate Amount Paid: 0.00 Previous Amount Paid: 0.00 In Network Accumulation: 0.00 Out of Network Accumulation: 0.00			
Med D Financials: LICs Paid by Plan: 0.00 SPAP/Integrator Paid Amt: 0.00 Reported Gap Discount: 0.00 Deductible Gross Cost: 0.00 Deductible Plan Pay: 0.00 Initial Gross Cost: 1043.10 Initial Plan Pay: 914.10 Gap Gross Cost: 0.00 Gap Plan Pay: 0.00 Catastrophic Gross Cost: 0.00 Catastrophic Plan Pay: 0.00					
View Settlement Codes View Comments		Back			
Pharmacy Reimbursement Reimbursement Type: Reimbursement Number: Reimbursement Amount: Posting Date: Reporting Number:		Recipient Name: Alternate Name: Address: City: State: Zip:			
Reversal Reimbursement Type: Reimbursement Number: Reimbursement Amount: Posting Date: Reporting Number: View Reimbursements		Go to top			

EXHIBIT 14

Implementation of the Single-Source Generic (SSG) Strategy includes several operational pieces to ensure exclusion of the generic product(s) and maximize the utilization of the rebated brand product.

The operational pieces that are updated for each drug in the SSG Strategy are the following:

- Update the QL shell plan for mail order to a Do Not Substitute (DNS) setup to block the auto-substitution of the brand for the generic
- TF Bypass list is updated to include the generic to prevent renewing members from receiving a transition fill on the generic when they have the brand product in history
- Brand products are added to the MAC Bypass List to allow pharmacies to continue being reimbursed for dispensing the brand, even if the generic is on the MAC list

Each of these operational pieces are coded at, or attached to, the Carrier level, which minimizes the risk inherent to group- or plan-level coding. At this time, Clearstone's account structure has Carriers (specifically 8635 and 8637) that are shared between plans that participate in SSG and plans that do not. As a result, for the plans not participating in SSG but sharing a Carrier with an SSG plan, there is the potential for impact to those areas:

- QL shell plans that are updated with an inappropriate DNS set up will result in prescriptions for branded products not auto-substituting for the covered generic, resulting in a rejected claim. If the mail order technicians do not catch the error and manually substitute for the generic product, the prescription could be returned to the member creating an access to care issue.
 - At this time, we believe there are 2 members in 2019 and 1 member in 2018 who was not able to receive their prescription via mail order as a result of the incorrect DNS setup.
- The TF Bypass applied to the incorrect plan could result in renewing members not receiving a transition fill for the generic product.
 - The impact of this should currently be zero as the generics for all drugs within the SSG strategy are currently covered on the Essential formulary. This does not result in a negative formulary change and transition fill is not triggered for the renewing members.
 - This will potentially cause member impact should the generic be removed from the formulary, as renewing members would be prevented from obtaining a transition fill of the generic.
- For those plans that are not participating in the SSG program, when the brand is added to the MAC Bypass List, any DAW penalties or MAC pricing will not apply for the brand where a brand is being dispensed. This results in failure to apply the DAW penalty to the member (if the plan has elected to have DAW penalties as part of their plan design) and potentially reimbursing the dispensing pharmacy at the brand rate, rather than at the MAC.

Because of the operational complexity involved with implementing the SSG Strategy, we have historically requested that clients elect the entire CAG structure into the SSG strategy. At this time, we are investigating options for accommodating Clearstone's current account structure for 2019 only. Moving forward into 2020, implementation of the SSG Strategy will need to take place at the Carrier level to decrease the complexity of implementation and maintenance as well as to minimize the risk associated with coding at the group or plan levels.

EXHIBIT 15

Y0080_72111_SCR_2017

MED D – <Copaxone> Generic not available on <Client> Formulary until further notice

[Overview](#)

[Rationale](#)

[What does this mean for the beneficiary?](#)

[Effects of this Strategy on Beneficiaries](#)

[FAQs](#)

[Log Activity](#)

[Resolution Time](#)

[Parent SOP](#)

Overview

<Copaxone> is a brand name prescription drug used to treat multiple sclerosis. This prescription drug was recently launched in its generic form <(glatiramer acetate)>.

Generic prescription drugs are typically the lowest-cost option when compared to brand name prescription drugs. <Client> promotes the use of generic prescription drugs to help plan beneficiaries save money.

- During the initial launch phase for the generic, there will be few manufacturers marketing the generic and the cost of the generic is expected to be relatively high. To help lower out-of-pocket

cost, <Client> is passing along a manufacturer discount on the brand <Copaxone>. As a result, <Client> will continue to keep the brand version of <Copaxone> on the formulary and will **NOT** be adding the generic version until further notice.

Network Pharmacies were also informed of this update.



- Effective immediately <Copaxone> will be maintained on Specialty Tier for <Client> formularies and the generic <(glatiramer acetate)> will not be added.

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Rationale

The goal of this document is to prepare the MED D Customer Care Representative (CCR) for potential inbound questions from the beneficiary regarding the release of <glatiramer acetate> and the non-covered status for this prescription drug in <Client> plans.

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What does this mean for the beneficiary?

- The beneficiary will continue to receive brand <Copaxone>.

NOTE: The generic equivalent, <Glatiramer acetate>, will not be on the formulary during this time.

- Beneficiaries will have the option to request an exception if they wish to obtain <glatiramer acetate>.
 - However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.
- Brand <Copaxone> is available at the current Specialty Tier copay/coinsurance, so if the request for the generic is granted, the beneficiary would pay the amount associated with the plan's exception tier. This may be a different cost than the brand.

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Effects of this Strategy on Beneficiaries

- Beneficiaries will continue to receive the brand <Copaxone> at the current Specialty tier copay/coinsurance.
- The CCR may receive calls from MED D beneficiaries who are confused about the lack of generic version availability of the prescription drug.
 - Refer to the [FAQs](#) section of this document for appropriate responses.

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FAQs

The following table of Frequently Asked Questions should assist the CCR when receiving a call from the beneficiary regarding this issue.

NOTE: These specifics apply to non-LICS beneficiaries. See specific Q&A at end of this FAQ section for LICS-specific information.

Question	Answer	
<p>Will <Copaxone> cost more than <glatiramer acetate> in any stage of the Medicare D benefit for non-LICS members?</p>	<p>SAY:</p> <ul style="list-style-type: none"> This will vary based on what Plan you are in and which Medicare Part D coverage stage you currently are in (e.g., Deductible, Initial Coverage Limit, Coverage Gap or Catastrophic). <p>CCR Process Note: The CCR will review the following grid for information on the anticipated costs of brand <Copaxone> vs. <glatiramer acetate> during the <glatiramer acetate> initial launch period:</p>	
	<p>Deductible Stage for non-LICS members:</p>	<p>SAY:</p> <ul style="list-style-type: none"> No.
	<p>Initial Coverage Limit (ICL) Stage for non-LICS members:</p>	<p>SAY:</p> <ul style="list-style-type: none"> Maybe. You will pay your current Specialty copay/coinsurance during the Initial Coverage Limit stage for brand <Copaxone>. <p>If appropriate: Mr. /Mrs. Beneficiary, your copayment for brand <Copaxone> will be <\$X.XX>.</p>

	<p>Coverage Gap Stage for non-LICS members:</p>	<p>SAY:</p> <ul style="list-style-type: none"> • No. • The Coverage Gap (donut hole) is where you will receive significant savings on brand <Copaxone>. • The brand name is less expensive than the generic version because of the manufacturer discount on brand name prescription drugs. • In the Coverage Gap stage, your cost share is <XX%> on the price of brand <Copaxone>. • If the generic were included at this time on the formulary, your cost share would be <XX%>.
--	---	--

	<p>Catastrophic Stage for non-LICS members:</p>	<p>SAY:</p> <ul style="list-style-type: none"> • Yes. • If you are already in the Catastrophic stage for <2017>, your overall cost for the year will not decrease. • During this stage of the benefit, you pay <X%> coinsurance. • Because of the anticipated price of the brand name compared to the generic, you will pay approximately <10% more> for brand <Copaxone> if you are already in the Catastrophic stage for <2017>. • If you have not yet reached the Catastrophic stage, your overall cost for brand <Copaxone> will be significantly less due to the cost savings that occur in the Coverage Gap stage (donut hole). • In <2018>, your overall savings over the course of the year could average between <\$1,100 and \$1, 400> for brand <Copaxone> based on the current estimated cost of the generic compared to the cost of brand <Copaxone>.
--	---	---

Aren't generics less expensive?	<p>SAY:</p> <ul style="list-style-type: none"> • When a generic version is first available, it is typically similar in price to the brand name version. • Eventually, we expect more generic prescription drug companies to start making and selling <glatiramer acetate>, which could bring down the price.
Can I get the generic?	<p>SAY:</p> <ul style="list-style-type: none"> • At this time the generic version, called <glatiramer acetate>, is not on the formulary. • You do have the option to request a formulary exception. However, brand <Copaxone> is available at the current Specialty Tier coinsurance/copay, so if the request for the generic is granted, you (the beneficiary) would pay the amount associated with the plan's exception tier. This may be a different cost than the brand. • Despite this unusual exception, we continue to encourage you to choose generic prescription drugs which often can save you money.
Will my other copays for other prescription drugs be lowered?	<p>SAY:</p> <ul style="list-style-type: none"> • No. • You will continue to pay the copay/coinsurance for other brand name and generic prescription drugs at the current benefit copayment.

<p>Are there other brand name prescription drugs that this applies to?</p>	<p>SAY:</p> <ul style="list-style-type: none"> • In most cases the generic version of a prescription drug is less expensive than the brand name version and is covered at the lower generic copay. • The exception typically applies during the first year the generic version of a prescription drug is launched.
<p>What should I do if brand <Copaxone> is removed from the formulary during the plan year?</p>	<p>SAY:</p> <ul style="list-style-type: none"> • We will provide you with prior notification if brand <Copaxone> is removed from the formulary during the Plan year. <ul style="list-style-type: none"> ○ • The type of notification depends on whether you are taking the prescription drug and whether the change happens during the plan year or at the beginning of the next plan year. <ul style="list-style-type: none"> ○ If we make this change during the plan year, and you are taking Copaxone we will give you written notice 60 days in advance of the change. This is usually provided in your Explanation of Benefits (EOB). ○ If we make this change at the beginning of the next plan year, the change will be noted in the formulary included as part of your Annual Notice of Change (ANOC) packet.

	<ul style="list-style-type: none"> ○ You should review your plan's formulary carefully. • If brand <Copaxone> is removed from the formulary and you want to continue taking brand <Copaxone>, you will have the option to request a formulary exception. <ul style="list-style-type: none"> ○ However, brand <Copaxone> is available at the current Specialty Tier copay, so if the request for the generic is granted, you (the beneficiary) would pay the amount associated with the plan's exception tier. This may be a different cost than the brand. 	
May I, as the beneficiary, request a coverage determination for the generic product?	SAY: <ul style="list-style-type: none"> • Yes, you as the beneficiary may request a coverage determination for <glatiramer acetate>. • However, brand <Copaxone> is available at the current Specialty Tier copay, so if the request for the generic is granted, you (the beneficiary) would pay the amount associated with the plan's exception tier. This may be a different cost than the brand. 	
Will <glatiramer acetate> be added to the formulary during the 2017 plan year?	SAY: <ul style="list-style-type: none"> • The addition of the generic to the formulary will be re-evaluated during the year. 	
Will <Copaxone> cost more than <(glatiramer acetate)> in any stage of the Medicare Part D benefit for LICS members?	CCR Process Note: The CCR will review the following information for LICS members on the anticipated costs of <Copaxone> vs. <glatiramer acetate> during the <glatiramer acetate> initial launch period:	
	For LICS 1 & 2 Members:	SAY: <ul style="list-style-type: none"> • Maybe.

		<ul style="list-style-type: none"> • In the Catastrophic stage of the benefit you will continue to receive <Copaxone> at no cost. • If you have not yet reached the Catastrophic stage, you might have to pay your brand name copayment for <Copaxone> until you reach the Catastrophic stage.
	For LICS 3 Members:	SAY: <ul style="list-style-type: none"> • No.
	For LICS 4 Members:	SAY: <ul style="list-style-type: none"> • Maybe. • If you are in the Initial Coverage Limit stage (ICL) or the Post-Initial Coverage stage of the benefit you will continue to pay your current coinsurance for <Copaxone>. • If you are in the Catastrophic stage, you will continue to pay the LIS brand name copayment for <Copaxone>.

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Log Activity

1003 – Plan Design Education

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Resolution Time

Information = immediate

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Parent SOP

CALL-0048: [Medicare Part D Customer Care Call Center Requirements- CVS Caremark Part D Services, L.L.C.](#)

[Top of the Document](#)

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EXHIBIT 16

Peoplesafe

Page 1 of 1

CAREMARK **PeopleSafe®** Close

Eligibility Maintenance ☐ Participant Inquiry ☐ Resolution Manager ☐ Medicare Inquiry ☐ View Opportunities Tools: -- Select A Tool --

Client: [REDACTED] SILVERSCRIPT-INDIV-ENROLL System: RXCLAIM

External ID: [REDACTED] Name: [REDACTED] Gndr: F Relationship: MEMBER Born: [REDACTED] 1952 Effective: 01-01-2019 Expiration: 12-31-2039

[Main Screen](#) [Financial Details](#) [View Activity](#) [Prescription History](#) [Test Claims](#) [Plan Benefit Override](#) [Account Balance](#) [Explanation of Benefits](#) [Transaction History](#) [Communication History](#) [Caremark.com](#)

[Pharmacy Network](#) [Retail Transaction](#) [Plan Summary](#) [FSA/HSA/HRA History](#) [Coordination of Benefits](#) [Order Placement](#) [Adjustments](#) [Client Managed \(G & A\)](#) [View Triggers](#)

Prescription for: [REDACTED] UNKNOWN Delivery System: POINT OF SALE
 Prescription Number: [REDACTED] [Go to Reimbursement...](#) Pharmacy NPI: [REDACTED] Dispense As Written: 0 - NO DAW
 Drug NDC: 378696112 Pharmacy NCPDP: [REDACTED] Drug Price Type: AVERAGE WHOLESALE PRICE
 Drug Name: GLATIRAMER ACETATE Pharmacy Name: CVS SPECIALTY [REDACTED] Drug Price Source: MEDISPAN
 Client Claim Price Type: Pharmacy Claim Price Type:

Participant Pay Participant Copay: 2242.69 Initial Copay: 1910.00 Gap Copay: 332.69 Catastrophic Copay: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 2242.69	Client Pay Usual and Customary: 11010.23 Cost Submitted: 4718.67 Cost Allowed: 0.00 Other Payer Recognized: 0.50 Dispensing Fee: 0.00 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 2476.48	Pharmacy Pay: Usual and Customary: 4718.67 Cost Allowed: 0.00 Other Payer Recognized: 0.50 Dispensing Fee: 0.00 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 2476.48
--	--	--

Health Reimbursement Account:
 Benefits: 0.00
 Member Access Fee: 0.00
 Amount Used: 0.00
 HRA Remaining Balance: 0.00

Med D Financials:
 LICs Paid by Plan: 0.00
 SPAP/Integrator Paid Amt: 0.00
 Reported Gap Discount: 0.00
 Deductible Gross Cost: 0.00
 Deductible Plan Pay: 0.00
 Initial Gross Cost: 3820.00
 Initial Plan Pay: 1910.00
 Gap Gross Cost: 899.17
 Gap Plan Pay: 566.48
 Catastrophic Gross Cost: 0.00
 Catastrophic Plan Pay: 0.00

Miscellaneous
 Applied To Out of Pocket: 0.00
 Applied To TROOP: 0.00
 Applied To OOPM/MOOP: 0.00
 Paid by Other Insurance: 0.00
 Alternate Amount Paid: 0.00
 Previous Amount Paid: 0.00
 In Network Accumulation: 0.00
 Out of Network Accumulation: 0.00

[View Settlement Codes](#) [View Comments](#) [Back](#)

Pharmacy Reimbursement

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

Reversal

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

[View Reimbursements](#)

Recipient

Name:
 Alternate Name:
 Address:
 City:
 State:
 Zip:

[Go to top](#)

EXHIBIT 17



P.O. Box 30013, Pittsburgh, PA 15222-0330

January 28, 2019

NE 6

**YOUR DRUG IS NOT ON OUR LIST OF COVERED DRUGS (FORMULARY)
OR IS SUBJECT TO CERTAIN LIMITS**

Dear [REDACTED]:

We want to tell you that SilverScript Choice (PDP) has provided you with a temporary supply of the following prescription: GLATIRAMER INJ 40MG/ML.

This drug is either not included on our list of covered drugs (called our formulary), or it's included on the formulary but subject to certain limits, as described in more detail later in this letter. SilverScript Choice (PDP) is required to provide you with a temporary supply of this drug. If your prescription is written for fewer than 30 days, we'll allow multiple fills to provide up to a maximum 30-day supply of medication.

It's important to understand that this is a temporary supply of this drug. Well before you run out of this drug, you should speak to SilverScript Choice (PDP) and/or the prescriber about:

- changing the drug to another drug that is on our formulary; or
- requesting approval for the drug by demonstrating that you meet our criteria for coverage; or
- requesting an exception from our criteria for coverage.

When you request approval for coverage or an exception from coverage criteria, these are called coverage determinations. Don't assume that any coverage determination, including any exception, you have requested or appealed has been approved just because you receive more fills of a drug. If we approve coverage, then we'll send you another written notice.

If you need assistance in requesting a coverage determination, including an exception, or if you want more information about when we will cover a temporary supply of a drug, contact us at 1-866-235-5660. TTY users should call 711. Live representatives are available 24 hours a day, 7 days a week. You can ask us for a coverage determination at any time. **Instructions on how to change your current prescription, how to ask for a coverage determination (including an exception), and how to appeal a denial if you disagree with our coverage determination are discussed at the end of this letter.**

The following is a specific explanation of why your drug is not covered or is limited.

Name of Drug: GLATIRAMER INJ 40MG/ML

Date Filled: 01/24/2019

Reason for Notification: This drug is not on our formulary. We will not continue to pay for this drug after you have received the maximum 30 days' temporary supply that we are required to cover unless you obtain a formulary exception from us.

How do I change my prescription?

If your drug is not on our formulary, or is on our formulary but we have placed a limit on it, you can ask us what other drug used to treat your medical condition is on our formulary, ask us to approve coverage by showing that you meet our criteria, or ask us for an exception. We encourage you to ask your prescriber if this other drug that we cover is an option for you. You have the right to request an exception from us to cover your drug that was originally prescribed. If you ask for an exception, your prescriber will need to provide us with a statement explaining why a prior authorization, quantity limit, or other limit we have placed on your drug is not medically appropriate for you.

How do I request a coverage determination, including an exception?

You or your prescriber may contact us to request a coverage determination, including an exception. The toll-free phone number is 1-866-235-5660 (TTY users should call 711), or you may fax to 1-855-633-7673, or you may write to us at: SilverScript Insurance Company Prescription Drug Plans Coverage Decisions and Appeals Department, P.O. Box 52000, MC 109, Phoenix, AZ 85072-2000. We are available 24 hours a day, 7 days a week.

If you are requesting coverage of a drug that is not on our formulary or an exception to a coverage rule, your prescriber must provide a statement supporting your request. It may be helpful to bring this notice with you to the prescriber or send a copy to his or her office. If the exception request involves a drug that is not on our formulary, the prescriber's statement must indicate that the requested drug is medically necessary for treating your condition because all of the drugs on our formulary would be less effective than the requested drug or would have adverse effects for you. If the exception request involves a prior authorization or other coverage rule we have placed on a drug that is on our formulary, the prescriber's statement must indicate that the coverage rule wouldn't be appropriate for you given your condition or would have adverse effects for you.

We must notify you of our decision no later than 24 hours, if the request has been expedited, or no later than 72 hours, if the request is a standard request, from when we receive your request. For exceptions, the timeframe begins when we obtain your prescriber's statement. Your request will be expedited if we determine, or your prescriber tells us, that your life, health, or ability to regain maximum function may be seriously jeopardized by waiting for a standard decision.

What if my request for coverage is denied?

If your request for coverage is denied, you have the right to appeal by asking for a review of the prior decision, which is called a redetermination. You must request this appeal within 60 calendar days from the date of our written decision on your coverage determination request. We accept standard and expedited requests by telephone and in writing. Contact us at: SilverScript Insurance Company Prescription Drug Plans Coverage Decisions and Appeals Department, P.O. Box 52000, MC 109, Phoenix, AZ 85072-2000; phone: 1-866-235-5660; TTY: 711; fax: 1-855-633-7673; 24 hours a day, 7 days a week.

If you need assistance in requesting a coverage determination, including an exception, or if you want more information about when we will cover a temporary supply of a drug, contact us at 1-866-235-5660, 24 hours a day, 7 days a week. TTY users should call 711. Live representatives are available 24 hours a day, 7 days a week. You can ask us for a coverage determination at any time. You can also visit our website at www.silverscript.com.

Sincerely,

SilverScript Choice (PDP)

The formulary may change at any time. You will receive notice when necessary.

Beneficiaries must use network pharmacies to access their prescription drug benefit.

ATENCIÓN: Si usted habla español, tenemos servicios de asistencia lingüística disponibles para usted sin costo alguno. Llame al 1-866-235-5660 (TTY: 711).

SilverScript is a Prescription Drug Plan with a Medicare contract offered by SilverScript Insurance Company. Enrollment in SilverScript depends on contract renewal.

SilverScript® Insurance Company complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. SilverScript Insurance Company does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

SilverScript Insurance Company:

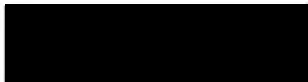
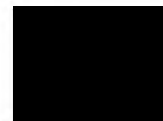
- § Provides free aids and services to people with disabilities to communicate effectively with us, such as:
 - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- § Provides free language services to people whose primary language is not English, such as:
 - Qualified interpreters
 - Information written in other languages

If you need written information in other formats or free language services, please contact Customer Care. This number can be found on the back of your member ID card or on the letter that accompanied this notice.

If you believe that SilverScript Insurance Company has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with: SilverScript Insurance Company, Grievance Department, P.O. Box 30016, Pittsburgh, PA 15222-0330. Fax: 1-866-217-3353.

You can file a grievance by mail, or by fax. If you need help filing a grievance, the SilverScript Grievance Department is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 1-800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.



ENGLISH

ATTENTION: If you speak English, language assistance services, free of charge, are available to you. Call 1-866-235-5660 (TTY*711).

SPANISH

ATENCIÓN: Si usted habla español, tenemos servicios de asistencia lingüística disponibles para usted sin costo alguno. Llame al 1-866-235-5660 (TTY: 711).

CHINESE

* * * * *
* * * * * 1-866-235-5660 (TTY:
711)*

VIETNAMESE

CHÚ Ý: Nếu quý vị nói tiếng Việt, thì có sẵn các dịch vụ trợ giúp ngôn ngữ miễn phí dành cho quý vị. Hãy gọi số 1-866-235-5660 (TTY: 711).

KOREAN

* * * * *
* * * * *
1-866-235-5660 (TTY: 711)* * * * *
* * * * *

TAGALOG

PANSININ: Kung nagsasalita po kayo ng Tagalog, magagamit ninyo ang mga serbisyong tulong sa wika ng walang bayad. Tawagan po ang *****235-5660 (TTY: 711).

RUSSIAN

ВНИМАНИЕ: Если вы говорите на русском языке, вам будут бесплатно предоставлены услуги переводчика. Звоните по телефону: 1-866-235-5660 (телетайп: 711).

ARABIC

ملاحظة: إذا كنت تتحدث العربية، تتوفر خدمات المساعدة اللغوية مجاناً. امن أهلك. اتصل بالرقم 1-866-235-5660 (الهاتف النصي: 711).

FRENCH CREOLE

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 1-866-235-5660 (TTY: 711).

FRENCH

ATTENTION : Si vous parlez français, des services gratuits d'interprétation sont à votre disposition. Veuillez appeler le 1-866-235-5660 (TTY: 711).

POLISH

UWAGA: Dla osób mówiących po polsku dostępna jest bezpłatna pomoc językowa. Zadzwoń pod numer 1-866-235-5660 (TTY: 711).

PORTUGUESE

ATENÇÃO: Se fala português, estão disponíveis serviços gratuitos de assistência linguística na sua língua. Telefone para 1-866-235-5660 (TTY: 711).

ITALIAN

ATTENZIONE: Se lei parla italiano, sono disponibili servizi gratuiti di assistenza linguistica nella sua lingua. Chiami 1-866-235-5660 (TTY: 711).

JAPANESE

* * * * *
* * * * *
* * * * * 1-866-235-5660 (TTY: 711) * *
* * * * *

GERMAN

BITTE BEACHTEN: Wenn Sie Deutsch sprechen, stehen Ihnen unsere Dolmetscher unter der Nummer 1-866-235-5660 (TTY: 711) kostenlos zur Verfügung.

FARSI

توجه: چنانچه به زبان فارسی صحبت می‌کنید، خدمات کمک زبانی، به صوار تریگا رد، نختیار شما قرارا خواهد گرفت. با شماره 1-866-235-5660 (TTY: 711) تماس بگیرید.

EXHIBIT 18

Peoplesafe

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CAREMARK **PeopleSafe®** Close

Eligibility Maintenance ☐ Participant Inquiry ☐ Resolution Manager ☐ Medicare D Inquiry ☐ View Opportunities Tools: -- Select A Tool --

Client: **SILVERSCRIPT-INDIV-ENROLL** System: **RXCLAIM**

External ID: **[REDACTED]** Name: **[REDACTED]** Gndr: **F** Relationship: **MEMBER** Born: **[REDACTED] 1952** Effective: **01-01-2019** Expiration: **12-31-2039**

[Main Screen](#) [Financial Details](#) [View Activity](#) [Prescription History](#) [Test Claims](#) [Plan Benefit Overview](#) [Account Balance](#) [Explanation of Benefits](#) [Transaction History](#) [Communication History](#) [Caremark.com](#)

[Pharmacy Network](#) [Retail Transaction](#) [Plan Summary](#) [FSA/HSA/HRA History](#) [Coordination of Benefits](#) [Order Placement](#) [Adjustments](#) [Client Managed \(G & A\)](#) [View Triggers](#)

Prescription for: **[REDACTED] UNKNOWN** Delivery System: **POINT OF SALE**
 Prescription Number: **[REDACTED]** [Go to Reimbursement...](#) Pharmacy NPI: **[REDACTED]**
 Drug NDC: **68546032512** Pharmacy NCPDP: **[REDACTED]** Dispense As Written: **1 - PHYSICIAN DAW**
 Drug Name: **COPAXONE** Pharmacy Name: **CVS SPECIALTY [REDACTED]** Drug Price Type: **AVERAGE WHOLESALE PRICE**
 Drug Price Source: **MEDISPAN** Client Claim Price Type: **[REDACTED]** Pharmacy Claim Price Type: **[REDACTED]**

Participant Pay Participant Copay: 294.65 Initial Copay: 0.00 Gap Copay: 0.00 Catastrophic Copay: 294.65 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 294.65	Client Pay Usual and Customary: 12247.20 Cost Submitted: 5892.65 Cost Allowed: 5892.65 Other Payer Recognized: 0.00 Dispensing Fee: 0.50 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 5598.50	Pharmacy Pay: Usual and Customary: 5892.65 Cost Allowed: 5892.65 Other Payer Recognized: 0.00 Dispensing Fee: 0.50 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 5598.50
---	---	---

Health Reimbursement Account:
 Benefits: 0.00
 Member Access Fee: 0.00
 Amount Used: 0.00
 HRA Remaining Balance: 0.00

Med D Financials:
 LICs Paid by Plan: 0.00
 SPAP/Integrator Paid Amt: 0.00
 Reported Gap Discount: 0.00
 Deductible Gross Cost: 0.00
 Deductible Plan Pay: 0.00
 Initial Gross Cost: 0.00
 Initial Plan Pay: 0.00
 Gap Gross Cost: 0.00
 Gap Plan Pay: 0.00
 Catastrophic Gross Cost: 5893.15
 Catastrophic Plan Pay: 5598.50

Miscellaneous
 Applied To Out of Pocket: 0.00
 Applied To TROOP: 0.00
 Applied To OOPM/MOOP: 0.00
 Paid by Other Insurance: 0.00
 Alternate Amount Paid: 0.00
 Previous Amount Paid: 0.00
 In Network Accumulation: 0.00
 Out of Network Accumulation: 0.00

[View Settlement Codes](#) [View Comments](#) [Back](#)

Pharmacy Reimbursement

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

Reversal

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

[View Reimbursements](#)

Recipient

Name:
 Alternate Name:
 Address:
 City:
 State:
 Zip:

[Go to top](#)

EXHIBIT 19

MED D - INVEGA® Generic Oral Tablet Not Available on SilverScript Choice, Plus, and Allure (PDP) Plans Until Further Notice

Y0080_72152_SCR_2019_v2

[Overview^L](#)

[Background^L](#)

[What does this mean for the Beneficiary?^L](#)

[Effects of this Strategy on the Beneficiaries^L](#)

[FAQs^L](#)

[Log Activity^L](#)

[Resolution Time^L](#)

[Related Documents^L](#)

[Parent SOP^L](#)

[Abbreviations / Definitions^L](#)

Overview

INVEGA® ORAL TABLET (pronounced in-VAY-ga) is a branded prescription drug commonly used for the treatment of schizophrenia. This prescription drug was recently launched in its generic form (paliperidone tablet) (PAL-uh-PEAR-uh-dohn). The generic form of INVEGA® TABLET is not available for SilverScript Choice, Plus, and Allure (PDP) plans until further notice.

INVEGA® TABLET will be MAINTAINED on the Preferred Brand Tier (Tier 3) in 2018 and 2019 for the formularies for SilverScript Choice, Plus, and Allure and the generic paliperidone tablet will **not** be added to the formularies.

This applies only to SilverScript Choice and Plus beneficiaries in 2018 and SilverScript Choice, Plus, and Allure beneficiaries in 2019.

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Background

Generic prescription drugs are typically the lowest-cost option when compared to branded prescription drugs. SilverScript **promotes the use of generic prescription drugs** to help plan beneficiaries save money.

- § During the initial launch phase for the generic, there will be few manufacturers marketing the generic and the cost of the generic is expected to be relatively high.
- § To help keep out-of-pocket costs low, SilverScript is retaining brand INVEGA TABLET on its formulary on the Preferred Brand Tier (Tier 3). INVEGA TABLET is eligible for a manufacturer discount in the coverage gap.
- § SilverScript will continue to keep the brand version of INVEGA TABLET on the formulary and will **NOT** be adding the generic version until further notice.

Network Pharmacies were also informed of this update.

Note: SilverScript Employer PDP Plans are being handled differently.

- § **SilverScript Choice, Plus, and Allure Plans**

The generic version of INVEGA (paliperidone) TABLET will **NOT** be added to the formularies for SilverScript Choice, Plus, and Allure plans.

- § **SilverScript Employer PDP Plans**

Employer PDP Plans have added the generic (paliperidone tablet) to their formulary for 2018 and 2019. Some plans will continue cover the brand in 2018 and 2019.

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What does this mean for the Beneficiary?

Retaining brand INVEGA TABLET on the Preferred Brand Tier (Tier 3) can help keep out-of-pocket costs low for SilverScript beneficiaries.

Note: The generic equivalent paliperidone tablet will **not** be on the formulary until further notice.

- § Beneficiaries will have the option to request a formulary exception if they wish to obtain paliperidone tablet.
 - However, exception requests for non-formulary prescription drugs, **if approved**, are typically approved for coverage at the **highest non-specialty** cost share level (Tier 4) in 2018 and 2019.
- § Brand INVEGA TABLET is available at Preferred Brand Tier (Tier 3) copay in 2018 and 2019, so if the request for the generic is granted, the beneficiary would most likely pay a higher out-of-pocket cost as the medication will pay as a Tier 4 coinsurance. As the cost of the generic is expected to be higher, the coinsurance amount will also be higher for the generic.

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Effects of this Strategy on the Beneficiaries

Beneficiaries will continue to receive the **brand** INVEGA TABLET, at the **Preferred Brand Tier (Tier 3)** copay.

Calls may be received from MED D beneficiaries who have questions regarding the lack of generic version availability of the prescription drug. Refer to the FAQs section of this document for appropriate responses.

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FAQs

The frequently asked questions below will assist the CCR when addressing incoming calls regarding INVEGA TABLET.


Note: These specifics apply to non-LIS beneficiaries. There is no impact expected to LIS beneficiaries. For LIS beneficiaries, if the brand has a generic available in the market, and the brand is in the preferred brand tier (with no market shortage), then it will adjudicate as the generic. **Exclusion:** Specialty.

Question	Answer	
Will INVEGA TABLET cost more than paliperidone tablet in any phase of the Medicare Part D benefit?	SAY: § This will vary based on your Plan and which Medicare Part D coverage stage you are currently in (e.g., Deductible, Initial Coverage Limit, Coverage Gap or Catastrophic).	
	CCR Process Note: Review the following grid for information on the anticipated costs of INVEGA TABLET vs. paliperidone tablet during the paliperidone tablet initial launch period:	
	<table> <tr> <td> Deductible Stage for non-LIS beneficiaries: </td><td> SilverScript Choice, Plus, and Allure beneficiaries: § In 2018, no deductible, except for Choice Plan beneficiaries residing in Alaska who will have a \$405 annual deductible and Choice Plan beneficiaries residing in Arizona and Hawaii who will have a \$100 annual deductible for drugs in Tiers 3 to 5. Plus Plan is not available in Alaska. § In 2019, no deductible except for Choice Plan beneficiaries who will have a \$100 annual deductible for drugs in Tiers 3 to 5 for beneficiaries residing in Colorado, Georgia, or Texas; Choice beneficiaries </td></tr> </table>	Deductible Stage for non-LIS beneficiaries:
Deductible Stage for non-LIS beneficiaries:	SilverScript Choice, Plus, and Allure beneficiaries: § In 2018, no deductible, except for Choice Plan beneficiaries residing in Alaska who will have a \$405 annual deductible and Choice Plan beneficiaries residing in Arizona and Hawaii who will have a \$100 annual deductible for drugs in Tiers 3 to 5. Plus Plan is not available in Alaska. § In 2019, no deductible except for Choice Plan beneficiaries who will have a \$100 annual deductible for drugs in Tiers 3 to 5 for beneficiaries residing in Colorado, Georgia, or Texas; Choice beneficiaries	

		<p>residing in Arizona, South Carolina, or Alaska will have a \$415 deductible for drugs in Tiers 3 to 5. SilverScript Plus and Allure Plans are not available in Alaska.</p> <p>Move to response below in Initial Coverage Phase.</p>
	<p>Initial Coverage Limits (ICL) Stage for non-LIS beneficiaries:</p>	<p>SAY:</p> <p>§ Maybe.</p> <p>§ You will continue to be pay a Preferred Brand Tier (Tier 3) copay in 2018 and 2019 during the Initial Coverage Stage for brand INVEGA® TABLET.</p> <p>§ Mr./Ms. Beneficiary, your copay for brand INVEGA® TABLET will be \$X.XX.</p> <p>Move to response below in Coverage Gap Stage.</p>
	<p>Coverage Gap Stage for non-LIS beneficiaries:</p>	<p>SAY:</p> <p>§ No.</p> <p>§ The Coverage Gap Stage (also called the “donut hole”) is where you will receive significant savings on brand INVEGA TABLET.</p> <p>§ The brand name is less expensive than the generic version because of the manufacturer discount on brand name prescription drugs.</p> <p>§ In 2018, your cost share in the Coverage Gap Stage is 35% on the price of brand INVEGA TABLET. If the generic were included at this time on the formulary, your cost share would be 44%.</p> <p>§ In 2019, your cost share in the Coverage Gap Stage is 25% on the price of brand INVEGA TABLET. If the</p>

		generic were included at this time on the formulary, your cost share would be 37%.
		Move to response below in Catastrophic Coverage Stage.
	Catastrophic Coverage Stage for non-LIS beneficiaries:	SAY: Yes. During this stage of the benefit, it is expected that - because of the price of the brand and generic versions - you will pay 5% of the allowed cost.
Why is the brand-name INVEGA TABLET on the Preferred Brand Tier (Tier 3) when there is now a generic available?	SAY: § In this case, the price of the generic version of INVEGA TABLET will likely be similar to the price of the brand version for a minimum of six months, and perhaps longer. § There are few manufacturers of the generic version of INVEGA TABLET to drive the price down. § Until there are competitors and the price of the generic version goes down, your plan will continue to cover brand-name INVEGA TABLET at the Preferred Brand Tier (Tier 3) copay in 2018 and 2019.	
Why can't I get the generic? Aren't generics less expensive?	SAY: § When a generic version is first available, it is typically similar in price to the brand version. § At this time the generic version, called paliperidone tablet, is not on the formulary. <ul style="list-style-type: none"> ○ You do have the option to request a formulary exception. ○ However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level (excluding the Specialty Tier - Tier 4) in 2018 and 2019. ○ Brand INVEGA TABLET is available at the Preferred Brand Tier (Tier 3) in 2018 and 2019, so even if an exception is granted to allow coverage of the 	

	<p>generic, you might pay more out-of-pocket for the generic version paliperidone tablet than for brand INVEGA TABLET.</p> <p>§ Eventually, we expect more generic prescription drug companies to start making and selling paliperidone tablet, and this should bring down the price.</p> <p>§ At that time, the generic version will be included on the formulary.</p>
Will my other copays for other prescription drugs be lowered?	<p>SAY:</p> <p>§ No.</p> <p>§ You will continue to pay the copay for other brand name prescription drugs at the current benefit copay. ^{III}</p>
Could there be other brand prescription drugs that this applies to?	<p>SAY:</p> <p>§ In most cases the generic version of a prescription drug is less expensive than the brand version and is covered at the lower generic copay.</p> <p>§ The exception typically applies during the first year the generic version of a prescription drug is launched.</p>
How long will INVEGA TABLET remain on the formulary in the Preferred Brand Tier?	<p>SAY:</p> <p>§ We anticipate that INVEGA TABLET will remain on the formulary in Preferred Brand Tier (Tier 3) in 2018 and 2019 until the price of the generic form of INVEGA TABLET drops.</p> <p>§ We anticipate it will be a minimum of six months, however that is based on market conditions not within our control and could change.</p>
What should I do when brand-name INVEGA TABLET is no longer available for Preferred Brand Tier (Tier 3) copay in 2018?	<p>SAY:</p> <p>§ We will provide you with prior notification if brand INVEGA TABLET is moved to a higher tier copay or removed from the formulary.</p> <p>§ The type of notification depends on whether the change happens during the plan year or at the beginning of the next plan year.</p> <ul style="list-style-type: none"> ○ If we make this change during the plan year, and you are taking INVEGA TABLET, we will give you written notice 60 days in advance of the change. This is usually provided in your Explanation of Benefits (EOB). ○ If we make this change at the beginning of the next plan year, the change

	<p>will be noted in the formulary included as part of your Annual Notice of Change (ANOC) packet.</p> <ul style="list-style-type: none"> ○ You should review your plan's formulary carefully. <p>§ Brand INVEGA TABLET may either be removed from the formulary or moved to a higher formulary tier.</p> <p>§ If you want to continue taking brand INVEGA TABLET you will have the option to request a formulary exception.</p> <p>§ However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level (excluding the specialty tier (Tier 5 in 2018 and 2019)).</p>
<p>May I, as the beneficiary, request a coverage determination for the generic product?</p>	<p>SAY:</p> <p>§ Yes, you as the beneficiary may request a coverage determination for paliperidone tablet.</p> <p>§ However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at a higher cost share level (excluding the specialty tier).</p> <p>§ Brand INVEGA TABLET is available at the Preferred Brand Tier (Tier 3) copay in 2018 and 2019, so you might pay more out-of-pocket for the generic than for the brand at this time.</p> <p> Refer to the Med D Care - Coverage Determination/Appeal (New or Status Update) document.</p>
<p>Will paliperidone tablet be added to the formulary during the 2019 plan year?</p>	<p>SAY:</p> <p>§ The addition of the generic to the formulary will be re-evaluated during the year.</p>

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Log Activity

1003 – Plan Design Education

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Resolution Time

Information = Immediate

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Related Documents

Grievance Standard Verbiage (for use in Discussion with Beneficiary) section in [MED D Care - Grievances in PeopleSafe and MedHOK](#)

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Parent SOP

CALL-0048: Medicare Part D Customer Care Call Center Requirements- CVS Caremark Part D Services, L.L.C.

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Abbreviations / Definitions

[Mail Service Customer Care Abbreviations and Definitions](#)

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ELECTRONIC DATA = OFFICIAL VERSION – PAPER COPY – INFORMATIONAL ONLY

EXHIBIT 20

Peoplesafe

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CAREMARK
Peoplesafe®
Close

[Eligibility Maintenance](#)
[Participant Inquiry](#)
[Resolution Manager](#)
[Medicare D Inquiry](#)

View Opportunities

Tools:
-- Select A Tool --

Client: [REDACTED] SILVERSCRIPT-INDIV-ENROLL System: RXCLAIM

External ID: [REDACTED] Name: [REDACTED] Gndr: M Relationship: MEMBER Born: [REDACTED]-1985 Effective: 01-01-2020 Expiration: 12-31-2039

[Main Screen](#)
[Financial Details](#)
[View Activity](#)
[Prescription History](#)
[Test Claims](#)
[Plan Benefit Override](#)
[Account Balance](#)
[Explanation of Benefits](#)
[Transaction History](#)
[Communication History](#)
[Carmark.com](#)

[Pharmacy Network](#)
[Retail Transaction](#)
[Plan Summary](#)
[FSA/HSA/HRA History](#)
[Coordination of Benefits](#)
[Order Placement](#)
[Adjustments](#)
[Client Managed G & A](#)
[View Triggers](#)

Prescription for: [REDACTED] MEMBER Delivery System: POINT OF SALE Dispense As Written: 0 - NO DAW

Prescription Number: [REDACTED] [Go to Reimbursement...](#) Pharmacy NPI: [REDACTED] Drug Price Type: MEDISPAN

Drug NDC: 10147095403 Pharmacy NCPDP: [REDACTED] Drug Price Source: [REDACTED]

Drug Name: PALUPERIDONE ER Pharmacy Name: [REDACTED] Client Claim Price Type: [REDACTED] Pharmacy Claim Price Type: [REDACTED]

Participant Pay Participant Copay: 3.40 Initial Copay: 405.37 Gap Copay: 0.00 Catastrophic Copay: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 3.40	Client Pay Usual and Customary: Cost Submitted: 1373.76 Cost Allowed: 810.25 Other Payer Recognized: 0.00 Dispensing Fee: 0.50 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 807.35	Pharmacy Pay: Usual and Customary: Cost Allowed: 810.25 Other Payer Recognized: 0.00 Dispensing Fee: 0.50 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 807.35
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Health Reimbursement Account: Benefits: 0.00 Member Access Fee: 0.00 Amount Used: 0.00 HRA Remaining Balance: 0.00	Miscellaneous Applied To Out of Pocket: 0.00 Applied To Troop: 0.00 Applied To OOPM/MOOP: 0.00 Paid by Other Insurance: 0.00 Alternate Amount Paid: 0.00 Previous Amount Paid: 0.00 In Network Accumulation: 0.00 Out of Network Accumulation: 0.00	Med D Financials: LICIS Paid by Plan: 401.97 SPAP/Integrator Paid Amt: 0.00 Reported Gap Discount: 0.00 Deductible Gross Cost: 0.00 Deductible Plan Pay: 0.00 Initial Gross Cost: 810.75 Initial Plan Pay: 405.38 Gap Gross Cost: 0.00 Gap Plan Pay: 0.00 Catastrophic Gross Cost: 0.00 Catastrophic Plan Pay: 0.00
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[View Comments](#)

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Pharmacy Reimbursement Reimbursement Type: Reimbursement Number: Reimbursement Amount: Posting Date: Reporting Number:	Recipient Name: Alternate Name: Address: City: State: Zip:
--	---

Reversal
 Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

View Reimbursements

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EXHIBIT 21



P.O. Box 30013, Pittsburgh, PA 15222-0330

February 26, 2019

**YOUR DRUG IS NOT ON OUR LIST OF COVERED DRUGS (FORMULARY)
OR IS SUBJECT TO CERTAIN LIMITS**

Dear [REDACTED]

We want to tell you that SilverScript Choice (PDP) has provided you with a temporary supply of the following prescription: PALIPERIDONE TAB ER 9MG.

This drug is either not included on our list of covered drugs (called our formulary), or it's included on the formulary but subject to certain limits, as described in more detail later in this letter. SilverScript Choice (PDP) is required to provide you with a temporary supply of this drug. If your prescription is written for fewer than 30 days, we'll allow multiple fills to provide up to a maximum 30-day supply of medication.

It's important to understand that this is a temporary supply of this drug. Well before you run out of this drug, you should speak to SilverScript Choice (PDP) and/or the prescriber about:

- changing the drug to another drug that is on our formulary; or
- requesting approval for the drug by demonstrating that you meet our criteria for coverage; or
- requesting an exception from our criteria for coverage.

When you request approval for coverage or an exception from coverage criteria, these are called coverage determinations. Don't assume that any coverage determination, including any exception, you have requested or appealed has been approved just because you receive more fills of a drug. If we approve coverage, then we'll send you another written notice.

If you need assistance in requesting a coverage determination, including an exception, or if you want more information about when we will cover a temporary supply of a drug, contact us at 1-866-235-5660. TTY users should call 711. Live representatives are available 24 hours a day, 7 days a week. You can ask us for a coverage determination at any time. **Instructions on how to change your current prescription, how to ask for a coverage determination (including an exception), and how to appeal a denial if you disagree with our coverage determination are discussed at the end of this letter.**

The following is a specific explanation of why your drug is not covered or is limited.

Name of Drug: PALIPERIDONE TAB ER 9MG

Date Filled: 02/22/2019

Reason for Notification: This drug is not on our formulary. We will not continue to pay for this drug after you have received the maximum 30 days' temporary supply that we are required to cover unless you obtain a formulary exception from us.

How do I change my prescription?

If your drug is not on our formulary, or is on our formulary but we have placed a limit on it, you can ask us what other drug used to treat your medical condition is on our formulary, ask us to approve coverage by showing that you meet our criteria, or ask us for an exception. We encourage you to ask your prescriber if this other drug that we cover is an option for you. You have the right to request an exception from us to cover your drug that was originally prescribed. If you ask for an exception, your prescriber will need to provide us with a statement explaining why a prior authorization, quantity limit, or other limit we have placed on your drug is not medically appropriate for you.

How do I request a coverage determination, including an exception?

You or your prescriber may contact us to request a coverage determination, including an exception. The toll-free phone number is 1-866-235-5660 (TTY users should call 711), or you may fax to 1-855-633-7673, or you may write to us at: SilverScript Insurance Company Prescription Drug Plans Coverage Decisions and Appeals Department, P.O. Box 52000, MC 109, Phoenix, AZ 85072-2000. We are available 24 hours a day, 7 days a week.

If you are requesting coverage of a drug that is not on our formulary or an exception to a coverage rule, your prescriber must provide a statement supporting your request. It may be helpful to bring this notice with you to the prescriber or send a copy to his or her office. If the exception request involves a drug that is not on our formulary, the prescriber's statement must indicate that the requested drug is medically necessary for treating your condition because all of the drugs on our formulary would be less effective than the requested drug or would have adverse effects for you. If the exception request involves a prior authorization or other coverage rule we have placed on a drug that is on our formulary, the prescriber's statement must indicate that the coverage rule wouldn't be appropriate for you given your condition or would have adverse effects for you.

We must notify you of our decision no later than 24 hours, if the request has been expedited, or no later than 72 hours, if the request is a standard request, from when we receive your request. For exceptions, the timeframe begins when we obtain your prescriber's statement. Your request will be expedited if we determine, or your prescriber tells us, that your life, health, or ability to regain maximum function may be seriously jeopardized by waiting for a standard decision.

What if my request for coverage is denied?

If your request for coverage is denied, you have the right to appeal by asking for a review of the prior decision, which is called a redetermination. You must request this appeal within 60 calendar days from the date of our written decision on your coverage determination request. We accept standard and expedited requests by telephone and in writing. Contact us at: SilverScript Insurance Company Prescription Drug Plans Coverage Decisions and Appeals Department, P.O. Box 52000, MC 109, Phoenix, AZ 85072-2000; phone: 1-866-235-5660; TTY: 711; fax: 1-855-633-7673; 24 hours a day, 7 days a week.

If you need assistance in requesting a coverage determination, including an exception, or if you want more information about when we will cover a temporary supply of a drug, contact us at 1-866-235-5660, 24 hours a day, 7 days a week. TTY users should call 711. Live representatives are available 24 hours a day, 7 days a week. You can ask us for a coverage determination at any time. You can also visit our website at www.silverscript.com.

Sincerely,

SilverScript Choice (PDP)

The formulary may change at any time. You will receive notice when necessary.

Beneficiaries must use network pharmacies to access their prescription drug benefit.

ATENCIÓN: Si usted habla español, tenemos servicios de asistencia lingüística disponibles para usted sin costo alguno. Llame al 1-866-235-5660 (TTY: 711).

SilverScript is a Prescription Drug Plan with a Medicare contract offered by SilverScript Insurance Company. Enrollment in SilverScript depends on contract renewal.

SilverScript® Insurance Company complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. SilverScript Insurance Company does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

SilverScript Insurance Company:

- § Provides free aids and services to people with disabilities to communicate effectively with us, such as:
 - Written information in other formats (large print, audio, accessible electronic formats, other formats)

- § Provides free language services to people whose primary language is not English, such as:
 - Qualified interpreters
 - Information written in other languages

If you need written information in other formats or free language services, please contact Customer Care. This number can be found on the back of your member ID card or on the letter that accompanied this notice.

If you believe that SilverScript Insurance Company has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with: SilverScript Insurance Company, Grievance Department, P.O. Box 30016, Pittsburgh, PA 15222-0330. Fax: 1-866-217-3353.

You can file a grievance by mail, or by fax. If you need help filing a grievance, the SilverScript Grievance Department is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 1-800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.



ENGLISH

ATTENTION: If you speak English, language assistance services, free of charge, are available to you. Call 1-866-235-5660 (TTY*711).

SPANISH

ATENCIÓN: Si usted habla español, tenemos servicios de asistencia lingüística disponibles para usted sin costo alguno. Llame al 1-866-235-5660 (TTY: 711).

CHINESE

* * * * *
* * * * * 1-866-235-5660 (TTY:
711)*

VIETNAMESE

CHÚ Ý: Nếu quý vị nói tiếng Việt, thì có sẵn các dịch vụ trợ giúp ngôn ngữ miễn phí dành cho quý vị. Hãy gọi số 1-866-235-5660 (TTY: 711).

KOREAN

* * * * *
* * * * *
1-866-235-5660 (TTY: 711)* * * * *
* * * * *

TAGALOG

PANSININ: Kung nagsasalita po kayo ng Tagalog, magagamit ninyo ang mga serbisyong tulong sa wika ng walang bayad. Tawagan po ang *****235-5660 (TTY: 711).

RUSSIAN

ВНИМАНИЕ: Если вы говорите на русском языке, вам будут бесплатно предоставлены услуги переводчика. Звоните по телефону: 1-866-235-5660 (телетайп: 711).

ARABIC

ملاحظة: إذا كنت تتحدث العربية، تتوفر خدمات المساعدة اللغوية مجاناً. امن أهلك. اتصل بالرقم 1-866-235-5660 (الهاتف النصي: 711).

FRENCH CREOLE

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 1-866-235-5660 (TTY: 711).

FRENCH

ATTENTION : Si vous parlez français, des services gratuits d'interprétation sont à votre disposition. Veuillez appeler le 1-866-235-5660 (TTY: 711).

POLISH

UWAGA: Dla osób mówiących po polsku dostępna jest bezpłatna pomoc językowa. Zadzwoń pod numer 1-866-235-5660 (TTY: 711).

PORTUGUESE

ATENÇÃO: Se fala português, estão disponíveis serviços gratuitos de assistência linguística na sua língua. Telefone para 1-866-235-5660 (TTY: 711).

ITALIAN

ATTENZIONE: Se lei parla italiano, sono disponibili servizi gratuiti di assistenza linguistica nella sua lingua. Chiami 1-866-235-5660 (TTY: 711).

JAPANESE

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* * * * *
* * * * * 1-866-235-5660 (TTY: 711) * *
* * * * *

GERMAN

BITTE BEACHTEN: Wenn Sie Deutsch sprechen, stehen Ihnen unsere Dolmetscher unter der Nummer 1-866-235-5660 (TTY: 711) kostenlos zur Verfügung.

FARSI

توجه: چنانچه به زبان فارسی صحبت میکنید، خدمات کمک زبانی، به صوار تریگا رد، نختیار شما قرارا خواهد گرفت. با شماره 1-866-235-5660 (TTY: 711) تماس بگیرید.

EXHIBIT 22

Peoplesafe

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CAREMARK		PeopleSafe®		Close	
Eligibility Maintenance	Participant Inquiry	Resolution Manager	Medicare Inquiry	View Opportunities	Tools: -- Select A Tool --
Client: SILVERSCRIPT-INDIV-ENROLL System: RXCLAIM External ID: Name: Gndr: M Relationship: MEMBER Born: 1985 Effective: 01-01-2020 Expiration: 12-31-2039					
Main Screen Financial Details View Activity Prescription History Test Claims Plan Benefit Overview Account Balance Explanation of Benefits Transaction History Communication History Caremark.com					
Pharmacy Network: Retail Transaction: Plan Summary: FSA/HSA/HRA History: Coordination of Benefits: Order Placement: Adjustments: Client Managed (G & A): View Triggers					
Prescription for: MEMBER Delivery System: POINT OF SALE Dispense As Written: 9 - PLAN REQ BRAND Prescription Number: Go to Reimbursement... Pharmacy NPI: Drug Price Type: AVERAGE WHOLESALE PRICE Drug NDC: 50458055201 Pharmacy NCPDP: Drug Price Source: MEDISPAN Drug Name: INVEGA Pharmacy Name: Client Claim Price Type: Pharmacy Claim Price Type:					
Participant Pay Participant Copay: 3.40 Initial Copay: 47.00 Gap Copay: 564.23 Catastrophic Copay: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 =====		Client Pay Usual and Customary: Cost Submitted: 2121.43 Cost Allowed: 1786.24 Other Payer Recognized: 0.00 Dispensing Fee: 0.50 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 1783.34		Pharmacy Pay: Usual and Customary: Cost Allowed: 1786.24 Other Payer Recognized: 0.00 Dispensing Fee: 0.50 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 1783.34	
Health Reimbursement Account: Benefits: 0.00 Member Access Fee: Amount Used: 0.00 HRA Remaining Balance: 0.00		Miscellaneous Applied To Out of Pocket: 0.00 Applied To TROOP: 0.00 Applied To OOPM/MOOP: 0.00 Paid by Other Insurance: 0.00 Alternate Amount Paid: 0.00 Previous Amount Paid: 0.00 In Network Accumulation: 0.00 Out of Network Accumulation: 0.00			
Med D Financials: LICs Paid by Plan: 607.83 SPAP/Integrator Paid Amt: 0.00 Reported Gap Discount: 0.00 Deductible Gross Cost: 0.00 Deductible Plan Pay: 0.00 Initial Gross Cost: 1222.51 Initial Plan Pay: 1175.51 Gap Gross Cost: 564.23 Gap Plan Pay: 0.00 Catastrophic Gross Cost: 0.00 Catastrophic Plan Pay: 0.00					
View Settlement Codes View Comments		Back			
Pharmacy Reimbursement Reimbursement Type: Reimbursement Number: Reimbursement Amount: Posting Date: Reporting Number:		Recipient Name: Alternate Name: Address: City: State: Zip:			
Reversal Reimbursement Type: Reimbursement Number: Reimbursement Amount: Posting Date: Reporting Number: View Reimbursements		Go to top			

EXHIBIT 23

MED D - ASACOL® HD DELAYED-RELEASE TABLETS Generic Not Available for SilverScript Choice, Plus, and Allure (PDP) Plans Until Further Notice Y0080_42115_SCR_2019

[Overview](#)

[Background](#)

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[Effects of this Strategy on Beneficiaries](#)

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[Abbreviations / Definitions](#)

Overview

ASACOL® HD DELAYED-RELEASE TABLETS is a branded prescription drug commonly used for the treatment of ulcerative colitis. This prescription drug was recently launched in its generic form, mesalamine delayed-release tablets. The generic form of ASACOL HD DELAYED-RELEASE TABLETS is not available on SilverScript Choice, Plus, or Allure (PDP) plans until further notice.

ASACOL® HD DELAYED-RELEASE TABLETS will be MAINTAINED on the Non-Preferred Drug Tier (Tier 4) in 2019 on the formularies for SilverScript Choice, Plus, and Allure beneficiaries. The generic, mesalamine delayed-release tablets, will **not** be added to the formularies.

This applies only to SilverScript Choice, Plus, and Allure beneficiaries in 2019.

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Background

Generic prescription drugs are typically the lowest-cost option when compared to branded prescription drugs. SilverScript **promotes the use of generic prescription drugs** to help plan beneficiaries save money.

- During the initial launch phase for the generic, there will be few manufacturers marketing the generic and the cost of the generic is expected to be relatively high.
- To help keep out-of-pocket costs low, SilverScript is retaining brand ASACOL® HD DELAYED-RELEASE TABLETS on its formulary on Non-Preferred Drug Tier (Tier 4). SilverScript will continue to keep the brand version of ASACOL HD DELAYED-RELEASE TABLETS on the formulary and will **NOT** be adding the generic version until further notice.

Network Pharmacies were also informed of this update.

Note: SilverScript Employer PDP Plans are being handled differently.

- **SilverScript Choice, Plus, and Allure Plans**
The generic version of ASACOL HD DELAYED-RELEASE TABLETS (mesalamine delayed-release tablets) will **NOT** be added to the SilverScript formularies for Choice, Plus, and Allure plans in 2019.
- **SilverScript Employer PDP Plans**
Employer PDP Plans have added the generic (mesalamine delayed-release tablets) to their formulary for 2019. Some plans will continue cover the brand in 2019.

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What does this mean for the beneficiary?

Retaining brand ASACOL HD DELAYED-RELEASE TABLETS on Non-Preferred Drug Tier (Tier 4) can help keep out-of-pocket costs low for SilverScript beneficiaries.

Note: The generic equivalent mesalamine delayed-release tablets is **not** be on the formulary until further notice.

- Beneficiaries have the option to request an exception if they wish to obtain mesalamine delayed-release tablets.
 - However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.
- Brand ASACOL HD DELAYED-RELEASE TABLETS is available at the Non-Preferred Drug Tier (Tier 4) copay/coinsurance, so if the request for the generic is granted, the beneficiary would pay the amount associated with the plan's exception tier. This may be a different cost than the brand.

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Effects of this Strategy on Beneficiaries

- Beneficiaries will continue to receive the brand ASACOL HD DELAYED-RELEASE TABLETS at the Non-Preferred Drug Tier (Tier 4) cost share.
- The CCR may receive calls from MED D beneficiaries who are confused about the lack of generic version availability of the prescription drug. Refer to the [FAQs](#) section of this document for appropriate responses.

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FAQs

The frequently asked questions below will assist the CCR when addressing incoming calls regarding ASACOL HD DELAYED-RELEASE TABLETS.

Note: These specifics apply to non-LIS beneficiaries. See specific Q&A at end of this FAQ section for LIS-specific information.


Question	Answer	
Will ASACOL HD DELAYED-RELEASE TABLETS cost more than mesalamine delayed-release tablets in any stage of the Medicare D benefit for non-LIS beneficiaries?	SAY: <ul style="list-style-type: none"> This will vary based on your Plan and which Medicare Part D coverage stage you currently are in (e.g., Deductible, Initial Coverage Limits, Coverage Gap or Catastrophic). CCR Process Note: The CCR will review the following grid for information on the anticipated costs of ASACOL HD DELAYED-RELEASE TABLETS vs. mesalamine delayed-release tablets during the mesalamine delayed-release tablets initial launch period:	
	Deductible Stage for non-LIS beneficiaries:	SilverScript Choice , Plus, and Allure beneficiaries: <ul style="list-style-type: none"> In 2019, no deductible except for Choice Plan beneficiaries who will have a \$100 annual deductible for drugs in Tiers 3 to 5 for beneficiaries residing in Colorado, Georgia, or Texas; Choice beneficiaries residing in Arizona and South Carolina will have a \$415 annual deductible for drugs in Tiers 3 to 5, or Alaska will have a \$415 deductible for all drugs. SilverScript Plus and Allure Plans do not have a deductible.

		Move to response below in Initial Coverage Limits Stage.
	Initial Coverage Limits (ICL) Stage for non-LIS beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> • Maybe. • You will continue to pay your current Non-Preferred Drug Tier (Tier 4) cost share during the Initial Coverage Limits stage for brand ASACOL HD DELAYED-RELEASE TABLETS. • Mr. /Mrs. <Beneficiary>, your cost share for brand ASACOL HD DELAYED-RELEASE TABLETS will be <\$X.XX>. <p>Move to response below in Coverage Gap Stage.</p>
	Coverage Gap Stage for non-LIS beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> • No. • The Coverage Gap Stage (also called the donut hole) is where you will receive significant savings on brand ASACOL HD DELAYED-RELEASE TABLETS. • The brand name is less expensive than the generic version because of the manufacturer discount on brand name prescription drugs. • In 2019, your cost share in the Coverage Gap Stage is 25% of the price of brand ASACOL HD DELAYED-RELEASE TABLETS. If the generic were included at this time on the formulary, your cost share would be 37%.

		Move to response below in Catastrophic Coverage Stage.
	Catastrophic Stage for non-LIS beneficiaries:	SAY: <ul style="list-style-type: none"> • Yes. • During this stage of the benefit, it is expected that - because of the price of the brand and generic versions - you will pay 5% of the allowed cost.
Why is the brand-name ASACOL HD DELAYED-RELEASE TABLETS on the formulary when there is now a generic available?		SAY: <ul style="list-style-type: none"> • In this case, the price of the generic version of ASACOL HD DELAYED-RELEASE TABLETS will likely be similar to the price of the brand version for a minimum of six months, and perhaps longer. • There are few manufacturers of the generic version of ASACOL HD DELAYED-RELEASE TABLETS to drive the price down. • Until there are competitors and the price of the generic version goes down, your plan will continue to cover brand-name ASACOL HD DELAYED-RELEASE TABLETS at the Non-Preferred Drug Tier (Tier 4) cost share in 2019.
Why can't I get the generic? Aren't generics less expensive?		SAY: <ul style="list-style-type: none"> • When a generic version is first available, it is typically similar in price to the brand version. • At this time the generic version, called mesalamine delayed-release tablets, is not on the formulary. <ul style="list-style-type: none"> ○ You do have the option to request a formulary exception. ○

	<ul style="list-style-type: none"> however, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.
Will my other copays for other prescription drugs be lowered?	SAY: <ul style="list-style-type: none"> No. You will continue to pay the copay/coinsurance for other brand name and generic prescription drugs at the current benefit copay.
Could there be other brand prescription drugs that this applies to?	SAY: <ul style="list-style-type: none"> In most cases the generic version of a prescription drug is less expensive than the brand name version and is covered at the lower generic copay. The exception typically applies during the first few years the generic version of a prescription drug is launched.
How long will ASACOL HD DELAYED-RELEASE TABLETS remain on the formulary on the Non-Preferred Drug Tier (Tier 4)?	SAY: <ul style="list-style-type: none"> We anticipate that ASACOL HD DELAYED-RELEASE TABLETS will remain on the formulary on the Non-Preferred Drug Tier (Tier 4) in 2019 until the price of the generic form of ASACOL HD DELAYED-RELEASE TABLETS drops. We anticipate it will be a minimum of six months, however that is based on market conditions not within our control and could change.
What should I do if brand ASACOL HD DELAYED-RELEASE TABLETS is removed from the formulary during the plan	SAY: <ul style="list-style-type: none"> We will provide you with prior notification if brand ASACOL HD DELAYED-RELEASE TABLETS removed from the formulary during the Plan year.

<p>year?</p>	<ul style="list-style-type: none"> • The type of notification depends on whether you are taking the prescription drug and whether the change happens during the plan year or at the beginning of the next plan year. <ul style="list-style-type: none"> ◦ If we make this change during the plan year, and you are taking ASACOL HD DELAYED-RELEASE TABLETS, you will receive written notification of the change in your Explanation of Benefits (EOB). ◦ If we make this change at the beginning of the next plan year, the change will be noted in the formulary included as part of your Annual Notice of Changes (ANOC) packet. ◦ You should review your plan's formulary carefully. • If brand ASACOL HD DELAYED-RELEASE TABLETS is removed from the formulary and you want to continue taking brand ASACOL HD DELAYED-RELEASE TABLETS, you will have the option to request a formulary exception. • However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.
<p>May I, as the beneficiary, request a coverage determination for the generic product?</p>	<p>SAY:</p> <ul style="list-style-type: none"> • Yes, you as the beneficiary may request a coverage determination for mesalamine delayed-release tablets. <ul style="list-style-type: none"> ◦ However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.

	 Refer to the Med D Care - Coverage Determination/Appeal (New or Status Update) document.	
Will mesalamine delayed-release tablets be added to the formulary during the 2019 plan year?	SAY: The addition of the generic to the formulary will be re-evaluated during the year.	
Will ASACOL HD DELAYED-RELEASE TABLETS cost more than mesalamine delayed-release tablets in any stage of the Medicare Part D benefit for LIS beneficiaries?	CCR Process Note: The CCR will review the following information for LIS beneficiaries on the anticipated costs of ASACOL HD DELAYED-RELEASE TABLETS vs. mesalamine delayed-release tablets during the mesalamine delayed-release tablets initial launch period:	
	For LIS 1 & 2 Beneficiaries:	SAY: <ul style="list-style-type: none"> • Maybe. • In the Catastrophic Coverage Stage of the benefit, you will continue to receive ASACOL HD DELAYED-RELEASE TABLETS at no cost. • If you have not yet reached the Catastrophic Coverage Stage, you might have to pay your brand name copayment for ASACOL HD DELAYED-RELEASE TABLETS until you reach the Catastrophic Coverage Stage.
	FOR LIS 3 Beneficiaries:	SAY: <ul style="list-style-type: none"> • No.
	FOR LIS 4 Beneficiaries:	SAY: <ul style="list-style-type: none"> • Maybe. • If you are in the Initial Coverage Limits Stage (ICL) or the Post-Initial Coverage Limits Stage of the benefit you will continue to pay your current coinsurance for ASACOL HD

		<ul style="list-style-type: none"> • DELAYED-RELEASE TABLETS. • If you are in the Catastrophic Coverage Stage, you will continue to pay the LIS brand name copayment for ASACOL HD DELAYED-RELEASE TABLETS.
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Log Activity

1003 – Plan Design Education

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Resolution Time

Information = immediate

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Related Documents

Grievance Standard Verbiage (for use in Discussion with Beneficiary) section in [MED D Care - Grievances in PeopleSafe and MedHOK](#)

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Parent SOP

CALL-0048: [Medicare Part D Customer Care Call Center Requirements- CVS Caremark Part D Services, L.L.C.](#)

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Abbreviations / Definitions

[Mail Service Customer Care Abbreviations and Definitions](#)

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EXHIBIT 24



Notice of Approval of Medicare Prescription Drug Coverage

Date: 11/08/2018

[REDACTED]

[REDACTED], FL [REDACTED]

Member Name: [REDACTED]

Member ID Number: [REDACTED]

Thank you for trusting your Medicare prescription drug coverage to SilverScript Choice (PDP). As our member, we want to help you get the most value from your prescription drug coverage and help you understand how your coverage works.

As a member of SilverScript Choice (PDP), we are pleased to inform you that, upon review of the information provided by you or your doctor, we have approved the requested coverage for the following prescription drug(s):

ASACOL HD Tablet DR

Type of coverage approved: Tier Change Requests

This approval authorizes your coverage from 08/10/2018 - 11/08/2019, unless we notify you otherwise, and as long as the following conditions apply:

- you remain enrolled in our Medicare Part D prescription drug plan,
- your physician or other prescriber continues to prescribe the medication for you, and
- the medication continues to be safe for treating your condition.

This approval authorizes you to receive the medication listed above at tier 02. Depending upon the strength and/or formulation of the drug prescribed by your physician, different quantity limits apply. Please consult your Medicare Part D plan's formulary for the specific quantity limit.

If you have not already filled your prescription for this approved drug, you may do so at a participating network pharmacy.

Thank you for allowing us to serve you. This letter is informational only. No further action is required by you at this time.

If you have questions or need help, please talk to your doctor or pharmacist, or contact Customer Care at 1-866-235-5660, 24 hours a day, 7 days a week. TTY users may call 711.

[REDACTED]

Thank you,

SilverScript Choice (PDP)

SilverScript is a Prescription Drug Plan with a Medicare contract offered by SilverScript Insurance Company. Enrollment in SilverScript depends on contract renewal.

EXHIBIT 25

Peoplesafe

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CAREMARK **PeopleSafe®** Close

Eligibility Maintenance **Participant Inquiry** Resolution Manager Medicare D Inquiry View Opportunities Tools: -- Select A Tool --

Client: **SILVERSCRIPT-INDIV-ENROLL** System: **RXCLAIM**

External ID: **[REDACTED]** Name: **[REDACTED]** Gndr: **F** Relationship: **MEMBER** Born: **[REDACTED] 1936** Effective: **04-01-2018** Expiration: **12-31-2039**

[Main Screen](#) [Financial Details](#) [View Activity](#) [Prescription History](#) [Test Claims](#) [Plan Benefit Overview](#) [Account Balance](#) [Explanation of Benefits](#) [Transaction History](#) [Communication History](#) [Caremark.com](#)

[Pharmacy Network](#) [Retail Transaction](#) [Plan Summary](#) [FSA/HSA/HRA History](#) [Coordination of Benefits](#) [Order Placement](#) [Adjustments](#) [Client Managed \(G & A\)](#) [View Triggers](#)

Prescription for: **[REDACTED] MEMBER** Delivery System: **POINT OF SALE** Dispense As Written: **1 - PHYSICIAN DAW**
 Prescription Number: **[REDACTED]** [Go to Reimbursement...](#) Pharmacy NPI: **[REDACTED]** Drug Price Type: **AVERAGE WHOLESALE PRICE**
 Drug NDC: **23590118** Pharmacy NCPDP: **[REDACTED]** Drug Price Source: **MEDISPAN**
 Drug Name: **ASAGOL HD** Pharmacy Name: **CVS PHARMACY [REDACTED]** Pharmacy Claim Price Type:

Participant Pay Participant Copay: 17.00 Initial Copay: 17.00 Gap Copay: 0.00 Catastrophic Copay: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 17.00	Client Pay Usual and Customary: Cost Submitted: 2031.00 Cost Allowed: 1706.04 Other Payer Recognized: 0.00 Dispensing Fee: 0.40 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 1689.44	Pharmacy Pay: Usual and Customary: Cost Allowed: 1706.04 Other Payer Recognized: 0.00 Dispensing Fee: 0.40 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 1689.44
--	--	---

Health Reimbursement Account:
 Benefits: 0.00
 Member Access Fee:
 Amount Used: 0.00
 HRA Remaining Balance: 0.00
 Capture Activity
Med D Financials:
 LICs Paid by Plan: 0.00
 SPAP/Integrator Paid Amt: 0.00
 Reported Gap Discount: 0.00
 Deductible Gross Cost: 0.00
 Deductible Plan Pay: 0.00
 Initial Gross Cost: 1706.44
 Initial Plan Pay: 1689.44
 Gap Gross Cost: 0.00
 Gap Plan Pay: 0.00
 Catastrophic Gross Cost: 0.00
 Catastrophic Plan Pay: 0.00

Miscellaneous
 Applied To Out of Pocket: 0.00
 Applied To TROOP: 0.00
 Applied To OOPM/MOOP: 0.00
 Paid by Other Insurance: 0.00
 Alternate Amount Paid: 0.00
 Previous Amount Paid: 0.00
 In Network Accumulation: 0.00
 Out of Network Accumulation: 0.00

[View Settlement Codes](#) [View Comments](#) [Back](#)

Pharmacy Reimbursement
 Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:
Reversal
 Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

[View Reimbursements](#)
Recipient
 Name:
 Alternate Name:
 Address:
 City:
 State:
 Zip:
[Go to top](#)

EXHIBIT 26

Peoplesafe

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CAREMARK **PeopleSafe®** Close

Eligibility Maintenance **N** Participant Inquiry **N** Resolution Manager **N** Medicare D Inquiry **N** View Opportunities Tools: -- Select A Tool --

Client: **SILVERSCRIPT-INDIV-ENROLL** System: **RXCLAIM**

External ID: **[REDACTED]** Name: **[REDACTED]** Gndr: **F** Relationship: **MEMBER** Born: **[REDACTED] 1936** Effective: **04-01-2018** Expiration: **12-31-2039**

Main Screen Financial Details View Activity Prescription History Test Claims Plan Benefit Override Account Balance Explanation of Benefits Transaction History Communication History Caremark.com

Pharmacy Network Retail Transaction Plan Summary FSA/HSA/HRA History Coordination of Benefits Order Placement Adjustments Client Managed (G & A) **View Triggers**

Prescription for: **[REDACTED] MEMBER** Delivery System: **POINT OF SALE** Dispense As Written: **1 - PHYSICIAN DAW**
 Prescription Number: **[REDACTED]** [Go to Reimbursement...](#) Pharmacy NPI: **[REDACTED]** Drug Price Type: **AVERAGE WHOLESALE PRICE**
 Drug NDC: **23590118** Pharmacy NCPDP: **[REDACTED]** Drug Price Source: **MEDISPAN**
 Drug Name: **ASAGOL HD** Pharmacy Name: **CVS PHARMACY [REDACTED]** Pharmacy Claim Price Type: **[REDACTED]**

Participant Pay Participant Copy: 345.73 Initial Copy: 17.00 Gap Copy: 328.73 Catastrophic Copy: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 345.73	Client Pay Usual and Customary: 2031.00 Cost Submitted: 1706.04 Cost Allowed: 1706.04 Other Payer Recognized: 0.00 Dispensing Fee: 0.40 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 1360.71	Pharmacy Pay: Usual and Customary: 1706.04 Cost Allowed: 1706.04 Other Payer Recognized: 0.00 Dispensing Fee: 0.40 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 1360.71
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Health Reimbursement Account:
 Benefits: 0.00
 Member Access Fee: 0.00
 Amount Used: 0.00
 HRA Remaining Balance: 0.00
 Capture Activity
Med D Financials:
 LICs Paid by Plan: 0.00
 SPAP/Integrator Paid Amt: 0.00
 Reported Gap Discount: 920.47
 Deductible Gross Cost: 0.00
 Deductible Plan Pay: 0.00
 Initial Gross Cost: 391.49
 Initial Plan Pay: 374.49
 Gap Gross Cost: 1314.95
 Gap Plan Pay: 986.22
 Catastrophic Gross Cost: 0.00
 Catastrophic Plan Pay: 0.00

Miscellaneous
 Applied To Out of Pocket: 0.00
 Applied To TROOP: 0.00
 Applied To OOPM/MOOP: 0.00
 Paid by Other Insurance: 0.00
 Alternate Amount Paid: 0.00
 Previous Amount Paid: 0.00
 In Network Accumulation: 0.00
 Out of Network Accumulation: 0.00

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Pharmacy Reimbursement
 Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:
Reversal
 Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

[View Reimbursements](#)
Recipient
 Name:
 Alternate Name:
 Address:
 City:
 State:
 Zip:
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EXHIBIT 27

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Speaker 1: Your dialed number was not entered within the allowed period. At the dial tone, please enter your number.

Eric Cartier: Hello? Hello? Hello?

Beneficiary 3: Hello.

Eric Cartier: Yes, ma'am, I'm sorry. I don't know what happened between the phone lines, but hey, my name is Eric. Thank you for calling the care reception review team. May I please have your-

Beneficiary 3: Hang on a second, Eric. What are you with?

Eric Cartier: I'm with the care reception review team, ma'am.

Beneficiary 3: With Silver Script?

Eric Cartier: Yes, ma'am.

Beneficiary 3: Okay. I just wanted to make sure I didn't get another company or something. Evidently I was being transferred to you and your transferring didn't go through like it was probably supposed to.

Eric Cartier: Yes, ma'am, most likely it did, because whoever transferred you was supposed to give me that information as well. But it's okay, [inaudible 00:01:05] stop our process. Could I please have your member ID?

Beneficiary 3: Member ID [REDACTED].

Eric Cartier: Yes, ma'am. And just to verify, that's [REDACTED], correct?

Beneficiary 3: No it's [REDACTED].

Eric Cartier: Okay.

Beneficiary 3: Not F.

Eric Cartier: Yes, ma'am, no problem. Sorry about that.

Beneficiary 3: That's okay.

Eric Cartier: You doing okay today, ma'am?

Beneficiary 3: Well, yeah, but I've got a problem that I need your help with. That's how I got you, because she must have transferred me. Just didn't tell me I was getting transferred.

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Eric Cartier: That's okay.

Beneficiary 3: Do you know my problem? Did she tell you?

Eric Cartier: No, ma'am, and that was one of the few things that she was supposed to send that information.

Beneficiary 3: Let me start all over then and tell you what happened, okay.

Eric Cartier: Okay, ma'am.

Beneficiary 3: I take a prescription, it's called Asacol, A-S-A-C-O-L.

Eric Cartier: Yes, ma'am.

Beneficiary 3: I got a letter from Silver Script that dates November 8th of 2018. And it said that I'd been approved for this drug through November 8th, 2019. And I went to the pharmacy to pick it up, and I've been paying \$17, and she told me today it's \$340, \$350. So what has changed, and who's right, who's wrong?

Eric Cartier: Yes, ma'am. So what I could do for you ... Okay, what I could do for you ... Well, first, would you like an alternative for this medicine, ma'am?

Beneficiary 3: Pardon?

Eric Cartier: Would you like an alternative to this medicine [inaudible 00:03:08]?

Beneficiary 3: Wait a minute, you're breaking up. I can't hear you. What?

Eric Cartier: I'm sorry about that, ma'am, you can hear me now?

Beneficiary 3: Yes.

Eric Cartier: Yes, ma'am, I asked, would you like an alternative for this medicine or would you like, that's similar to this medicine but a different brand, or would you like to keep this particular medicine?

Beneficiary 3: Well, that's a question for my doctor.

Eric Cartier: Yes, ma'am. See, what I could do is I could give you the alternatives for this medicine and you could call and check basis with your doctor concerning of the medicine so he can verify it for you that it will be healthy for you. We could start with that process as soon as you give me the go, ma'am.

Beneficiary 3: Well, why did I get a letter saying it was settled through November of 2019? And this is like the second or third month I go to get it, and I I've already got a problem.

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Eric Cartier: That is true, ma'am, that is true. So would you like to proceed with the process of going on board to keep this medicine?

Beneficiary 3: Well, I don't want to go into it with my doctor, that's for sure. I just had a doctor's appointment that took me almost three hours. It's a very busy doctor's group and it's not easy to get anything worked out. So what is the problem? Why do I have the problem today when I haven't had it for three, four months?

Eric Cartier: Yes, ma'am. The problem is it's saying that you have to discuss your balance with ... The opportunity to save based on this medicine. I want to say that's the problem, and yes, and you are correct, your prior authorization back on November the 8th of 2019. So that is not the problem. So it seems to be from my information that I have that I'm looking at, that all you need is to talk to a member of my coverage determination team so they could be able to further assist you on this.

Beneficiary 3: Now, you have totally lost me in what you're explaining. I do not know how Silver Script works since I've never worked for them.

Eric Cartier: Yes, ma'am.

Beneficiary 3: So what do I have to do to go to the drug store and get my prescription? Because I've only got medicine for one more day.

Eric Cartier: Yes, ma'am, no problem. See, what I have to do is, what I'm going to do for you is transfer you to my coverage determination team so they can give you further assistance on keeping this medicine and trying to get a tier section for this medicine so you can have it below price.

Beneficiary 3: Well, it also says I have a tier change. Wait a minute, where is it? Where does it say that? "This approval authorizes you to receive the medication listed above at tier two, depending upon on the strength and/or formulation of the drug prescribed by your physician."

Eric Cartier: Yes, ma'am.

Beneficiary 3: So what do I have ... I don't understand how it's been working for three, four months and all of a sudden now I have a problem. And they've already told me I've got it through November 8th of 2019 unless we notify you otherwise. And I haven't been notified by your company. And it says you were enrolled in the Medicare part D, which I am. My physician or another prescriber continues the medication for me. And I just discussed it with him today, so he did. And the medication continues to be safe for treating my condition. So according to the letter, I don't know why I have a problem today. And I'm not picking on you.

Eric Cartier: Yes, ma'am, trust me. I understand that you're just in concern of your medicine because you need it. And I'm totally aware that that is the situation. So for us to

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go forward so you could keep this medicine, right? You would like to keep this medicine, right?

Beneficiary 3: Well, I don't see any reason to change. If I'm going to change, I've got to evidently go back to the doctor. I don't know these medicines you're talking about. So I don't know if they're going to be the same for me or not. I'm not a pharmacist, I'm not in any way educated other than how to put them in my mouth and swallow them with water. So I'm not the one that can make the decision about whether or not it can be changed. That has to go through my doctor.

Eric Cartier: And that is right, ma'am. Do you by chance have a number for your doctor?

Beneficiary 3: I can give it to you if you want to wait one minute until I get, I think I have his card right here on my desk. Hang on a second.

Eric Cartier: Yes, ma'am.

Beneficiary 3: I wasn't picking on you, and I don't mean to be nasty to you, because I know it's not you any more than it's me. We're the pawns in between.

Eric Cartier: No, ma'am, no problem. I'm here to help, ma'am, I am here to help and I'm here to solve the problem. So that's what I was saying, if you have your doctor's office number, I could give you those alternatives and you could call him to verify with him to see, would that medicine be [inaudible 00:09:09].

Beneficiary 3: Yeah, but I'm not proficient in discussing medicines. I don't know one from another. What if he doesn't understand which one you're talking about?

Eric Cartier: Yes, ma'am, because I was going to give you the spelling and every detail of the strength of the medicine.

Beneficiary 3: Can't the insurance company call the doctor's office to see if it can be substituted?

Eric Cartier: Yes, ma'am, but the only way I have, the only way that the insurance would have to call the doctor, for my knowledge, is that I have to transfer you to my coverage determination team and they'll give you further assistance.

Beneficiary 3: Wait a minute, what team is that? What team is that? I'm sorry, I didn't understand that part. Hello?

Eric Cartier: Yes, ma'am, it's my coverage determination team.

Beneficiary 3: Determination. Well, see, I'm not going to be able to explain anything to ...

Eric Cartier: No, ma'am, you won't have to.

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Beneficiary 3: ... Doctor and a prescription company, and I'm in no position to know what in the hell I'm talking about.

Eric Cartier: Yes, ma'am, you won't have to tell the coverage determination team anything. I would be the one that would be telling them and updating them on what's going on.

Beneficiary 3: Now, can they call the doctor? Do they have that ability to call the doctor if they need to talk to their office?

Eric Cartier: Yes, ma'am.

Beneficiary 3: Okay. Then I guess you might as well transfer me or do whatever you need to do, because I've only got one more day of medicine and then I'm out.

Eric Cartier: Yes, ma'am, no problem. Okay, can I please put you on a brief hold for a moment while I contact them?

Beneficiary 3: Absolutely.

Eric Cartier: Okay, thank you for your patience too as well, okay, ma'am?

Beneficiary 3: Okay. Thank you too for not getting upset with me.

Eric Cartier: No, ma'am, no, ma'am. Like I say, I'm here to help, okay?

Beneficiary 3: Thank you.

Beneficiary 3: (silence)

Speaker 4: Thank you for calling CVS Health. For quality purposes this call may be monitored or recorded.

Cynthia: Thank you for calling CVS Caremark. My name is Cynthia, CD&E representative. May I have the member ID, please?

Eric Cartier: Yes, ma'am, it's [REDACTED].

Cynthia: Thank you. Name and date of birth?

Eric Cartier: The date of birth will be, one moment, [REDACTED].

Cynthia: And what's the full name?

Eric Cartier: The full name is, one moment, [REDACTED].

Cynthia: Is she on the other line for [inaudible 00:13:59]?

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Eric Cartier: Yes, ma'am.

Cynthia: And is she transferred for a tier or a non-formulary exception?

Eric Cartier: Tier.

Cynthia: For what medication?

Eric Cartier: Asacol.

Cynthia: You said she wants a tier exception for it, right?

Eric Cartier: Yes, ma'am.

Cynthia: Could I get your name, initial, and your [inaudible 00:14:36] ID?

Eric Cartier: Yes, ma'am. My name is Eric. One moment, ma'am, could you please allow me one second to check on the member?

Cynthia: Sure.

Eric Cartier: Okay, thank you. Yes, ma'am, [REDACTED] ?

Beneficiary 3: Yes?

Eric Cartier: Yes, ma'am, I am on the other line with the coverage determination team, and all I have to do is give them a [inaudible 00:15:06] and then I'll be able to transfer you over, okay, [REDACTED] ?

Beneficiary 3: All you have to do is give them what?

Eric Cartier: All I have to do is give them a few more information, they need a few more information, and then I'll be able to transfer you over, okay?

Beneficiary 3: Okay. That's fine, I'm waiting. No problem.

Eric Cartier: Yes, ma'am, thank you for being patient with me, okay?

Beneficiary 3: Sure.

Eric Cartier: All right. Yes, ma'am, you here?

Cynthia: Mm-hmm.

Eric Cartier: Yes, ma'am, and you was asking for my information, correct?

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Cynthia: Mm-hmm.

Eric Cartier: Yes, ma'am, my information is Eric C, Z267972.

Cynthia: Hm. Okay. For that medication I'm showing there's a case on file that's approved for her already.

Eric Cartier: Yes, ma'am, but she's saying that when she went in for this medicine particularly, that she usually be paying \$17, and today for some reason it was more expensive, it was \$343.

Cynthia: Okay. Did you check and see why it was more expensive or what's going on?

Eric Cartier: Yes, ma'am, I actually did. One moment so I could pull up back the account. One moment, ma'am, I'm sorry. Yes, ma'am, it says, "Discuss GNRC savings opportunity with member."

Cynthia: Okay.

Eric Cartier: And it says prior authorization expires on November the 8th 2019.

Cynthia: Okay. So what's the reason for the price being so high? I can't explain that to her. We've already approved a tier exception request for that medication, it's approved at a tier two. The price that's coming up, I have no idea why it's doing that. That's not something we can figure out.

Eric Cartier: So ...

Cynthia: Do they have a deductible? Is there an amount that they need to meet first?

Eric Cartier: No, ma'am, [inaudible 00:18:07]. GNRC savings opportunity with member.

Cynthia: I'm so sorry, I have a bad connection with you. What was that?

Eric Cartier: Yes, ma'am, the only thing that it says on my end is discuss GNRC savings opportunity with member.

Cynthia: Okay.

Eric Cartier: So did you run a test claim, ma'am?

Cynthia: I'm sorry?

Eric Cartier: Did you run a test claim?

Cynthia: For what?

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Eric Cartier: For the medicine.

Cynthia: I know, but why, like for what?

Eric Cartier: So you'll be able to see the information I'm telling you.

Cynthia: No, I'm getting a paid claim. I'm getting a paid claim, it's going through, it's paid, and it's covered. The pricing, I cannot verify pricing, we have a tier exception approved already for her.

Eric Cartier: So is the pricing saying \$345.73?

Cynthia: I cannot verify pricing.

Eric Cartier: So I'm just confused, ma'am, what I'm supposed to tell my ...

Cynthia: I mean, you need to figure out why the price is so high. I don't figure that out. We already approved a tier exception for the medication. So I don't know what you want me to do. I can't create a new one because there's already one approved until 11/8/2019. It's been approved. Are they in the gap coverage, maybe? I don't know.

Eric Cartier: Yes, ma'am, one moment while I check into the account, okay?

Cynthia: Okay.

Cynthia: (silence)

Eric Cartier: Yes, ma'am, you here?

Cynthia: Mm-hmm.

Eric Cartier: Ma'am?

Cynthia: Mm-hmm.

Eric Cartier: You here?

Cynthia: Yes?

Eric Cartier: Okay. Yes, ma'am, well, I do see that, yes, you are correct, she is in a gap at the moment. So thank you for your assistance. I'll give her the information that she needs to know, okay?

Cynthia: Okay. Well, even though we have a tier exception on file and it's approved, it's kind of like it's not even there. It doesn't apply until they meet the gap first.

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Eric Cartier: Okay. Yes, ma'am.

Cynthia: All right. You have a great day.

Eric Cartier: You do too.

Cynthia: Bye.

Eric Cartier: Yes, ma'am, [REDACTED] ?

Beneficiary 3: Yes?

Eric Cartier: Yes, ma'am, okay. Yes, ma'am. It appears that you were, you already had, like you said, a tier exception, and I see that you're currently in the, how could I say? You're in a gap. And you may be eligible to get extra help paying for your prescription drugs, the Medicare prescription drug program gives you a choice of prescription plans that offer various various types of coverage. In addition, you may be able to get extra help to pay for the monthly premiums and your deductibles. Excuse me, ma'am, I'm sorry, and copayments related to the Medicare prescription drug program. But before we can help you, you must fill out this application, put it in the enclosed envelope, and mail it today. Or you may complete an online application at www.socialsecurity.gov. We will review your application and send you a letter to let you to let you know if your quantity for extra help. I'm sorry, ma'am, to let you know if you qualify for extra help to use the extra-

Beneficiary 3: But why did they approve it and send me the letter if they wanted to go through all of this? Why in the hell didn't you do it when it started?

Eric Cartier: Yes, I'm not sure on that, ma'am.

Beneficiary 3: No, I got a letter from you saying I'm covered through, what did I tell you the date was? November 8th of 2019. But you did say unless we notify you otherwise. Well, why did you tell my doctor's office then that this was all taken care of?

Eric Cartier: Yes, ma'am, well, like I said, you are covered for it, you is covered, you just have a copay of ...

Beneficiary 3: No, the drug store is telling me if I want it it's \$350-something.

Eric Cartier: Yes, ma'am, it's \$345.73.

Beneficiary 3: And that's not what I've been paying. I've been paying \$17.

Eric Cartier: Yes, ma'am.

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Beneficiary 3: What is the difference? What is going on with your company?

Eric Cartier: I'm not sure, ma'am. But like I said, if you need help completing this application, you can call the Social Security office, 1-800-

Beneficiary 3: Tell me what I do after tomorrow when I have no medicine? I have enough for one day. It's the end of the prescription. And I went to pick up the next month. You did not send me a letter telling me anything changed. Don't you think they have to approve the prescription so I at least have a month to figure out what in the hell I'm going to do?

Eric Cartier: Yes, ma'am, you is correct about that.

Beneficiary 3: So who can approve it for the drug store so they can sell it to me as they did the previous month, and now all of a sudden I have a problem?

Eric Cartier: Yes, ma'am. And again, I'm truly sorry about that. But like I say, you may be eligible to get extra help paying for your prescription drugs.

Beneficiary 3: Yeah, if I fill out papers, mail them in to you, you decide with your determination team or whatever. But what I'm telling you is I have no pills after tomorrow. Don't you think as a company you should have at least given me a month's notice that this was going to happen?

Eric Cartier: Yes, ma'am, that is correct.

Beneficiary 3: So who can do something about it to give me a month to get it straightened out?

Eric Cartier: Well, one moment, ma'am, let me look into the account, okay?

Beneficiary 3: Yes.

Beneficiary 3: (silence)

Eric Cartier: Yes, ma'am, I'm still here. I'm just looking into the account, okay?

Beneficiary 3: Yes. Okay.

Eric Cartier: Thank you for your patience, ma'am.

Beneficiary 3: That's okay. Take your time.

Beneficiary 3: (silence)

Eric Cartier: Yes ma'am, you here, [REDACTED]

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Beneficiary 3: I'm here.

Eric Cartier: Yes, ma'am, I thank you for patiently holding and being patient with me.

Beneficiary 3: That's okay.

Eric Cartier: Yes, ma'am, and as I looked into the account, like I said, you are in a coverage ... I'm sorry, ma'am, you will go into the coverage gap. And the only option that I can give you for now is the alternative, or I could give you an alternative maybe for a lower cost of the medication, or I could give you some websites that you could look onto that will be helpful for you as well.

Beneficiary 3: What are the alternative medicines that you said they were talking about?

Eric Cartier: Yes, ma'am, one moment as I pull up that information, okay?

Beneficiary 3: Okay. I'm losing all respect for Silver Script. Why in the hell they send a letter like that and then two months later don't tell you and let you go to the drug store and find out that they're not going to do it any more.

Eric Cartier: And again, ma'am, I'm sorry that happened to you.

Beneficiary 3: I know, thank you, but it certainly isn't speaking well of Silver Script. At least they could have sent me a letter that said, "As of this date it's not going to be available as it is," and give me time to figure out what in the heck to do. Instead they wait until I'm out of a prescription and go to buy the new one and then say, "Oh, but you paid \$17 for it, now we want \$345." I think you'd feel the same way if it was you.

Eric Cartier: Yes, ma'am. Yes, ma'am.

Beneficiary 3: Could have been a better way to handle it than to send me the damn letter covering the whole year and then change their mind.

Eric Cartier: Yes, ma'am. I'm looking into the alternatives, okay?

Beneficiary 3: Uh-huh (affirmative).

Eric Cartier: And yes, ma'am, you take this medicine two times a day, correct?

Beneficiary 3: Three times a day. Two pills three times a day. So that's two, four, six pills a day I take.

Eric Cartier: Of this medicine?

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Beneficiary 3: Yes. Yeah, my other prescriptions, they're like \$2 a month for 90 days rather than a month. So this is the only medicine that I have to take that is exorbitant in its price. But that's the pharmaceutical companies.

Eric Cartier: And again, ma'am, like I say, I truly understand your concern of what's going on. So please don't think that I'm just ...

Beneficiary 3: Yeah, I know. You'd feel the same if you were in my position or if your mother was. You'd feel the same way.

Eric Cartier: And that is correct.

Beneficiary 3: The thing of it is that Silver Script didn't think enough of me to send me a damn letter and tell me that they weren't going to supply it.

Eric Cartier: Yes, ma'am.

Beneficiary 3: [crosstalk 00:39:11].

Eric Cartier: Yes, ma'am. So I do have some alternatives here.

Beneficiary 3: Okay. Could you give me two or three of them?

Eric Cartier: Yes, ma'am. I have-

Beneficiary 3: You'll have to spell them for me.

Eric Cartier: Yes, ma'am. I have one of them is A-P-R-I-S-O.

Beneficiary 3: Wait a minute. A ...

Eric Cartier: P-R.

Beneficiary 3: R.

Eric Cartier: I-S-O.

Beneficiary 3: That's it?

Eric Cartier: Yes, ma'am, cap 0.375.

Beneficiary 3: Wait a minute. What was it again? I'm sorry. I was talking when you did.

Eric Cartier: Cap 0.375GM

Beneficiary 3: 0.375?

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Eric Cartier: GM.

Beneficiary 3: G-M, G as in George, M as in Mary?

Eric Cartier: Yes, ma'am.

Beneficiary 3: Okay. Let me make sure I got this right. A-T-R-I-S-O, cap 0.37, G as in George, M as in Mary?

Eric Cartier: Yes, ma'am. And it's A-P, P as in Paul.

Beneficiary 3: P as in Paul, where's that?

Eric Cartier: It's A-P.

Beneficiary 3: A-T as in Tom or A-P as in Paul?

Eric Cartier: A-P as in Paul.

Beneficiary 3: Okay. Okay. A as Alice, P as in Paul, R as in Robert, I as in Ida, S as in Sam, O as in O?

Eric Cartier: Correct.

Beneficiary 3: Okay. That's the first one?

Eric Cartier: Yes, ma'am. And the second one is sulfadiazine. S-U ...

Beneficiary 3: Okay, you'll have to spell it for me.

Eric Cartier: S-U-L-F-A-D.

Beneficiary 3: S-A-D.

Eric Cartier: I.

Beneficiary 3: I as in Ida?

Eric Cartier: Yes, ma'am.

Beneficiary 3: Okay.

Eric Cartier: A as in apple, Z.

Beneficiary 3: Okay.

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Eric Cartier: I-N-E.

Beneficiary 3: Okay. Let me make sure. S as in Sam, A as in Alice, D as in David, I as in Ida, A as in Alice, Z as in zoo, R as in Robert, N as in Nancy, E as in Edward.

Eric Cartier: Yes, ma'am.

Beneficiary 3: Okay. And is that a cap also, capsule?

Eric Cartier: No, ma'am, that's a tab.

Beneficiary 3: A tab?

Eric Cartier: Yes, ma'am.

Beneficiary 3: And what's the dosage on it?

Eric Cartier: The dosage is 500 milligrams.

Beneficiary 3: 500 milligrams. Okay. Well, what I'll do is call my doctor's office and have them check those two, see if either one will do what the other does. And in the meantime, so Silver Script is telling me tough luck for my medicine beyond tomorrow, right? Right? Did you have-

Eric Cartier: Oh, I'm sorry, ma'am, no, ma'am, I'm sorry, I had the phone mistakenly on mute. But yes, ma'am, you are correct.

Beneficiary 3: So in other words, I'm out of luck if the doctor doesn't pick one of these two?

Eric Cartier: Yes, ma'am.

Beneficiary 3: All right. Thanks for your help.

Eric Cartier: You're welcome, ma'am. Is there anything else I could do for you?

Beneficiary 3: No, Silver Script's done enough. Thanks a lot.

Eric Cartier: Okay. Yes, ma'am.

Beneficiary 3: Okay, bye.

Eric Cartier: Thank you, and have a nice day.

EXHIBIT 28

MED D – RENVELA® ORAL PACKETS Generic Not Available for SilverScript Choice, Plus, and Allure (PDP) Plans Until Further Notice Y0080_42124_SCR_2019

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Overview

RENVELA® ORAL PACKETS is a branded prescription drug commonly used for the treatment of high potassium in the blood; RENVELA works by binding phosphates in the stomach, preventing them from being absorbed in the body. This prescription drug was recently launched in its generic form sevelamer carbonate oral packets. The generic form of RENVELA ORAL PACKETS is not available on SilverScript Choice, Plus, or Allure (PDP) plans until further notice.

RENVELA ORAL PACKETS will be MAINTAINED on the Preferred Brand Tier (Tier 3) in 2019 on the formularies for SilverScript Choice, Plus, and Allure beneficiaries. The generic, sevelamer carbonate oral packets, will **not** be added to the formularies.

This applies only to SilverScript Choice, Plus, and Allure beneficiaries in 2019.

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Background

Generic prescription drugs are typically the lowest-cost option when compared to branded prescription drugs. SilverScript **promotes the use of generic prescription drugs** to help plan beneficiaries save money.

- During the initial launch phase for the generic, there will be few manufacturers marketing the generic and the cost of the generic is expected to be relatively high.
- To help keep out-of-pocket costs low, SilverScript is retaining brand RENVELA ORAL PACKETS on its formulary on Preferred Brand Tier (Tier 3). RENVELA is eligible for a manufacturer discount in the coverage gap.
- SilverScript will continue to keep the brand version of RENVELA ORAL PACKETS on the formulary and will **NOT** be adding the generic version until further notice.

Network Pharmacies were also informed of this update.

Note: SilverScript Employer PDP Plans are being handled differently.

- **SilverScript Choice, Plus, and Allure Plans**

The generic version of RENVELA ORAL PACKETS (sevelamer carbonate oral packets) will **NOT** be added to the SilverScript formularies for Choice, Plus, and Allure plans in 2019.

- **SilverScript Employer PDP Plans**

Employer PDP Plans have added the generic (sevelamer carbonate oral packets) to their formulary for 2019. Some plans will continue cover the brand in 2019.

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What does this mean for the beneficiary?

Retaining brand RENVELA ORAL PACKETS on Preferred Brand Tier (Tier 3) can help keep out-of-pocket costs low for SilverScript beneficiaries.

Note: The generic equivalent sevelamer carbonate oral packets is **not** be on the formulary until further notice.

- Beneficiaries have the option to request an exception if they wish to obtain sevelamer carbonate oral packets.
 - However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.
- Brand RENVELA ORAL PACKETS is available at the Preferred Brand Tier (Tier 3) copay/coinsurance, so if the request for the generic is granted, the beneficiary would pay the amount associated with the plan's exception tier. This may be a different cost than the brand.

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Effects of this Strategy on Beneficiaries

- Beneficiaries will continue to receive the brand RENVELA at the Preferred Brand (Tier 3) copay/coinsurance.
- The CCR may receive calls from MED D beneficiaries who are confused about the lack of generic version availability of the prescription drug. Refer to the [FAQs](#) section of this document for appropriate responses.

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FAQs

The frequently asked questions below will assist the CCR when addressing incoming calls regarding RENVELA ORAL PACKETS.


Note: These specifics apply to non-LIS beneficiaries. See specific Q&A at end of this FAQ section for LIS-specific information.

Question	Answer	
Will RENVELA ORAL PACKETS cost more than sevelamer carbonate oral packets in any stage of the Medicare D benefit for non-LIS beneficiaries?	SAY: <ul style="list-style-type: none"> This will vary based on your Plan and which Medicare Part D coverage stage you currently are in (e.g., Deductible, Initial Coverage Limits, Coverage Gap or Catastrophic). CCR Process Note: The CCR will review the following grid for information on the anticipated costs of RENVELA ORAL PACKETS vs. sevelamer carbonate oral packets during the sevelamer carbonate oral packets initial launch period:	
	Deductible Stage for non-LIS beneficiaries:	SilverScript Choice , Plus, and Allure beneficiaries: <ul style="list-style-type: none"> In 2019, no deductible except for Choice Plan beneficiaries who will have a \$100 annual deductible for drugs in Tiers 3 to 5 for beneficiaries residing in Colorado, Georgia, or Texas; Choice beneficiaries residing in Arizona and South Carolina will have a \$415 annual deductible for drugs in Tiers 3 to 5, or Alaska will have a \$415 deductible for all drugs. SilverScript Plus and Allure Plans do not have a deductible.

		Move to response below in Initial Coverage Limits Stage.
	Initial Coverage Limits (ICL) Stage for non-LIS beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> • Maybe. • You will continue to pay your current Preferred Brand (Tier 3) copay during the Initial Coverage Limits stage for brand RENVELA ORAL PACKETS. • Mr. /Mrs. <Beneficiary>, your copayment for brand RENVELA will be <\$X.XX>. <p>Move to response below in Coverage Gap Stage.</p>
	Coverage Gap Stage for non-LIS beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> • No. • The Coverage Gap Stage (also called the donut hole) is where you will receive significant savings on brand RENVELA ORAL PACKETS. • In 2019, your cost share in the Coverage Gap Stage is 25% of the price of brand RENVELA ORAL PACKETS. If the generic were included at this time on the formulary, your cost share would be 37%. <p>Move to response below in Catastrophic Coverage Stage.</p>
	Catastrophic Stage for non-LIS	<p>SAY:</p> <ul style="list-style-type: none"> • Yes.

	beneficiaries: <ul style="list-style-type: none"> During this stage of the benefit, it is expected that - because of the price of the brand and generic versions - you will pay 5% of the allowed cost.
Why is the brand-name RENVELA ORAL PACKETS on the formulary when there is now a generic available?	SAY: <ul style="list-style-type: none"> In this case, the price of the generic version of RENVELA ORAL PACKETS will likely be similar to the price of the brand version for a minimum of six months, and perhaps longer. There are few manufacturers of the generic version of RENVELA ORAL PACKETS to drive the price down. Until there are competitors and the price of the generic version goes down, your plan will continue to cover brand-name RENVELA at the Preferred Brand Tier (Tier 3) copay/coinsurance in 2019.
Why can't I get the generic? Aren't generics less expensive?	SAY: <ul style="list-style-type: none"> When a generic version is first available, it is typically similar in price to the brand version. At this time the generic version, called sevelamer carbonate oral packets, is not on the formulary. <ul style="list-style-type: none"> You do have the option to request a formulary exception. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.
Will my other copays for other prescription drugs be lowered?	SAY: <ul style="list-style-type: none"> No. You will continue to pay the copay/coinsurance for other brand name

	<ul style="list-style-type: none"> • and generic prescription drugs at the current benefit copay.
Could there be other brand prescription drugs that this applies to?	<p>SAY:</p> <ul style="list-style-type: none"> • In most cases the generic version of a prescription drug is less expensive than the brand name version and is covered at the lower generic copay. • The exception typically applies during the first few years the generic version of a prescription drug is launched.
How long will RENVELA ORAL PACKETS remain on the formulary on the Preferred Brand Tier (Tier 3)?	<p>SAY:</p> <ul style="list-style-type: none"> • We anticipate that RENVELA ORAL PACKETS will remain on the formulary on the Preferred Brand Tier (Tier 3) in 2019 until the price of the generic form of RENVELA drops. • We anticipate it will be a minimum of six months, however that is based on market conditions not within our control and could change.
What should I do if brand RENVELA ORAL PACKETS is removed from the formulary during the plan year?	<p>SAY:</p> <ul style="list-style-type: none"> • We will provide you with prior notification if brand RENVELA ORAL PACKETS removed from the formulary during the Plan year. • The type of notification depends on whether you are taking the prescription drug and whether the change happens during the plan year or at the beginning of the next plan year. <ul style="list-style-type: none"> ○ If we make this change during the plan year and you are taking RENVELA ORAL PACKETS, you will receive written notification of the change in your Explanation of Benefits (EOB). ○ If we make this change at the beginning of the next plan year,

	<ul style="list-style-type: none"> ○ he change will be noted in the formulary included as part of your Annual Notice of Changes (ANOC) packet. ○ You should review your plan's formulary carefully. • If brand RENVELA ORAL PACKETS is removed from the formulary and you want to continue taking brand RENVELA, you will have the option to request a formulary exception. • However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.
May I, as the beneficiary, request a coverage determination for the generic product?	<p>SAY:</p> <ul style="list-style-type: none"> • Yes, you as the beneficiary may request a coverage determination for sevelamer carbonate oral packets. <ul style="list-style-type: none"> ○ However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level. <p> Refer to the Med D Care - Coverage Determination/Appeal (New or Status Update) document.</p>
Will sevelamer carbonate oral packets be added to the formulary during the 2019 plan year?	<p>SAY:</p> <p>The addition of the generic to the formulary will be re-evaluated during the year.</p>
Will RENVELA cost more than sevelamer carbonate oral packets in any stage of the Medicare Part D	<p>CCR Process Note: The CCR will review the following information for LIS beneficiaries on the anticipated costs of RENVELA ORAL PACKETS vs. sevelamer carbonate oral packets during the sevelamer carbonate oral packets initial launch period:</p>

benefit for LIS beneficiaries?	
	<p>For LIS 1 & 2 Beneficiaries:</p> <p>SAY:</p> <ul style="list-style-type: none"> • Maybe. • In the Catastrophic Coverage Stage of the benefit, you will continue to receive RENVELA ORAL PACKETS at no cost. • If you have not yet reached the Catastrophic Coverage Stage, you might have to pay your brand name copayment for RENVELA ORAL PACKETS until you reach the Catastrophic Coverage Stage.
	<p>FOR LIS 3 Beneficiaries:</p> <p>SAY:</p> <ul style="list-style-type: none"> • No.
	<p>FOR LIS 4 Beneficiaries:</p> <p>SAY:</p> <ul style="list-style-type: none"> • Maybe. • If you are in the Initial Coverage Limits Stage (ICL) or the Post-Initial Coverage Limits Stage of the benefit you will continue to pay your current coinsurance for RENVELA ORAL PACKETS. • If you are in the Catastrophic Coverage Stage, you will continue to pay the LIS brand name copayment for RENVELA ORAL PACKETS.

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Log Activity

1003 – Plan Design Education

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Resolution Time

Information = immediate

[Top of the Document](#)

Related Documents

Grievance Standard Verbiage (for use in Discussion with Beneficiary) section in [MED D Care - Grievances in PeopleSafe and MedHOK](#)

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Parent SOP

CALL-0048: [Medicare Part D Customer Care Call Center Requirements- CVS Caremark Part D Services, L.L.C.](#)

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Abbreviations / Definitions

[Mail Service Customer Care Abbreviations and Definitions](#)

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EXHIBIT 29

MED D – RENVELA® TABLETS Generic Not Available for SilverScript Choice, Plus, and Allure (PDP) Plans Until Further Notice Y0080_42124_SCR_2019

[Overview](#)

[Background](#)

[What does this mean for the beneficiary?](#)

[Effects of this Strategy on Beneficiaries](#)

[FAQs](#)

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Overview

RENVELA TABLETS is a branded prescription drug commonly used for the treatment of high potassium in the blood; RENVELA works by binding phosphates in the stomach, preventing them from being absorbed in the body. This prescription drug was recently launched in its generic form, sevelamer carbonate tablets. The generic form of RENVELA TABLETS is not available on SilverScript Choice, Plus, or Allure (PDP) plans until further notice.

RENVELA TABLETS will be MAINTAINED on the Preferred Brand Tier (Tier 3) in 2019 on the formularies for SilverScript Choice, Plus, and Allure beneficiaries. The generic (sevelamer carbonate tablets) will **not** be added to the formularies.

This applies only to SilverScript Choice, Plus, and Allure beneficiaries in 2019.

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Background

Generic prescription drugs are typically the lowest-cost option when compared to branded prescription drugs. SilverScript **promotes the use of generic prescription drugs** to help plan beneficiaries save money.

- During the initial launch phase for the generic, there will be few manufacturers marketing the generic and the cost of the generic is expected to be relatively high.
- To help keep out-of-pocket costs low, SilverScript is retaining brand RENVELA TABLETS on its formulary on Preferred Brand Tier (Tier 3). RENVELA TABLETS is eligible for a manufacturer discount in the coverage gap.
- SilverScript will continue to keep the brand version of RENVELA TABLETS on the formulary and will **NOT** be adding the generic version until further notice.

Network Pharmacies were also informed of this update.

Note: SilverScript Employer PDP Plans are being handled differently.

- **SilverScript Choice, Plus, and Allure Plans**
The generic version of RENVELA TABLETS (sevelamer carbonate tablets) will **NOT** be added to the SilverScript formularies for SilverScript Choice, Plus, and Allure plans in 2019.
- **SilverScript Employer PDP Plans**
Employer PDP Plans have added the generic (sevelamer carbonate tablets) to their formulary for 2019. Some plans will continue cover the brand in 2019.

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What does this mean for the beneficiary?

Retaining brand RENVELA TABLETS on Preferred Brand Tier (Tier 3) can help keep out-of-pocket costs low for SilverScript beneficiaries.

Note: The generic equivalent sevelamer carbonate tablets is **not** be on the formulary until further notice.

- Beneficiaries have the option to request an exception if they wish to obtain sevelamer carbonate tablets.
 - However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.
- Brand RENVELA TABLETS is available at the Preferred Brand Tier (Tier 3) copay/coinsurance, so if the request for the generic is granted, the beneficiary would pay the amount associated with the plan's exception tier. This may be a different cost than the brand.

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Effects of this Strategy on Beneficiaries

- Beneficiaries will continue to receive the brand RENVELA TABLETS at the Preferred Brand (Tier 3) copay/coinsurance.
- The CCR may receive calls from MED D beneficiaries who are confused about the lack of generic version availability of the prescription drug. Refer to the [FAQs](#) section of this document for appropriate responses.

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FAQs

The frequently asked questions below will assist the CCR when addressing incoming calls regarding RENVELA TABLETS.

Note: These specifics apply to non-LIS beneficiaries. See specific Q&A at end of this FAQ section for LIS-specific information.


Question	Answer
<p>Will RENVELA TABLETS cost more than sevelamer carbonate tablets in any stage of the Medicare D benefit for non-LIS beneficiaries?</p>	<p>SAY:</p> <ul style="list-style-type: none"> • This will vary based on your Plan and which Medicare Part D coverage stage you currently are in (e.g., Deductible, Initial Coverage Limits, Coverage Gap or Catastrophic). <p>CCR Process Note: The CCR will review the following grid for information on the anticipated costs of RENVELA TABLETS vs. sevelamer carbonate tablets during the sevelamer carbonate tablets initial launch period:</p>
<p>Deductible Stage for non-LIS beneficiaries:</p>	<p>SilverScript Choice , Plus, and Allure beneficiaries:</p> <ul style="list-style-type: none"> • In 2019, no deductible except for Choice Plan beneficiaries who will have a \$100 annual deductible for drugs in Tiers 3 to 5 for beneficiaries residing in Colorado, Georgia, or Texas; Choice beneficiaries residing in Arizona, South Carolina will have a \$415 annual deductible for drugs in Tiers 3 to 5, or Alaska will have a \$415 deductible for drugs in all Tiers. SilverScript Plus and Allure Plans are do not have a deductible. <p>Move to response below in Initial Coverage Limits Stage.</p>
<p>Initial Coverage Limits (ICL) Stage for non-LIS beneficiaries:</p>	<p>SAY:</p> <ul style="list-style-type: none"> • Maybe. • You will continue to pay your current Preferred Brand (Tier 3) copay during the Initial Coverage Limits stage for brand RENVELA TABLETS.

	<ul style="list-style-type: none"> Mr. /Mrs. <Beneficiary>, your copayment for brand RENVELA TABLETS will be <\$X.XX>. <p>Move to response below in Coverage Gap Stage.</p>
Coverage Gap Stage for non-LIS beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> No. The Coverage Gap Stage (also called the donut hole) is where you will receive significant savings on brand RENVELA TABLETS. The brand name is less expensive than the generic version because of the manufacturer discount on brand name prescription drugs. In 2019, your cost share in the Coverage Gap Stage is 25% of the price of brand RENVELA TABLETS. If the generic were included at this time on the formulary, your cost share would be 37%. <p>Move to response below in Catastrophic Coverage Stage.</p>
Catastrophic Stage for non-LIS beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> Yes. During this stage of the benefit, it is expected that - because of the price of the brand and generic versions - you will pay 5% of the allowed cost.
Why is the brand-name RENVELA TABLETS on the formulary when there is now a generic available?	<p>SAY:</p> <ul style="list-style-type: none"> In this case, the price of the generic version of RENVELA TABLETS will likely be similar to the price of the brand version for a minimum of six months, and perhaps longer. There are few manufacturers of the generic version of RENVELA TABLETS to drive the price

	<ul style="list-style-type: none"> • own. • Until there are competitors and the price of the generic version goes down, your plan will continue to cover brand-name RENVELA TABLETS at the Preferred Brand Tier (Tier 3) copay/coinsurance in 2019.
Why can't I get the generic? Aren't generics less expensive?	<p>SAY:</p> <ul style="list-style-type: none"> • When a generic version is first available, it is typically similar in price to the brand version. • At this time the generic version, called sevelamer carbonate tablets, is not on the formulary. <ul style="list-style-type: none"> ○ You do have the option to request a formulary exception. ○ However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.
Will my other copays for other prescription drugs be lowered?	<p>SAY:</p> <ul style="list-style-type: none"> • No. • You will continue to pay the copay/coinsurance for other brand name and generic prescription drugs at the current benefit copay.
Could there be other brand prescription drugs that this applies to?	<p>SAY:</p> <ul style="list-style-type: none"> • In most cases the generic version of a

	<ul style="list-style-type: none"> • prescription drug is less expensive than the brand name version and is covered at the lower generic copay. • The exception typically applies during the first few years the generic version of a prescription drug is launched.
How long will RENVELA TABLETS remain on the formulary on the Preferred Brand Tier (Tier 3)?	<p>SAY:</p> <ul style="list-style-type: none"> • We anticipate that RENVELA TABLETS will remain on the formulary on the Preferred Brand Tier (Tier 3) in 2019 until the price of the generic form of RENVELA TABLETS drops. • We anticipate it will be a minimum of six months, however that is based on market conditions not within our control and could change.
What should I do if brand RENVELA TABLETS is removed from the formulary during the plan year?	<p>SAY:</p> <ul style="list-style-type: none"> • We will provide you with prior notification if brand RENVELA TABLETS removed from the formulary during the Plan year. • The type of notification depends on whether you are taking the prescription drug and whether the change happens during the plan year or at the beginning of the next plan year. <ul style="list-style-type: none"> ◦ If we make this change during the plan

	<ul style="list-style-type: none"> ○ ear and you are taking RENVELA TABLETS, you will receive written notification of the change in your Explanation of Benefits (EOB). ○ If we make this change at the beginning of the next plan year, the change will be noted in the formulary included as part of your Annual Notice of Changes (ANOC) packet. ○ You should review your plan's formulary carefully. • If brand RENVELA TABLETS is removed from the formulary and you want to continue taking brand RENVELA TABLETS, you will have the option to request a formulary exception. • However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.
<p>May I, as the beneficiary, request a coverage determination for the generic product?</p>	<p>SAY:</p> <ul style="list-style-type: none"> • Yes, you as the beneficiary may request a coverage determination for sevelamer carbonate tablets. <ul style="list-style-type: none"> ○ However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the

	<ul style="list-style-type: none"> highest cost share level. <p> Refer to the Med D Care - Coverage Determination/Appeal (New or Status Update) document.</p>
Will sevelamer carbonate tablets be added to the formulary during the 2019 plan year?	<p>SAY: The addition of the generic to the formulary will be re-evaluated during the year.</p>
Will RENVELA TABLETS cost more than sevelamer carbonate tablets in any stage of the Medicare Part D benefit for LIS beneficiaries?	<p>CCR Process Note: The CCR will review the following information for LIS beneficiaries on the anticipated costs of RENVELA TABLETS vs. <(FULL_GENERIC_NAME)> during the sevelamer carbonate tablets initial launch period:</p>
For LIS 1 & 2 Beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> Maybe. In the Catastrophic Coverage Stage of the benefit, you will continue to receive RENVELA TABLETS at no cost. If you have not yet reached the Catastrophic Coverage Stage, you might have to pay your brand name copayment for RENVELA TABLETS until you reach the Catastrophic Coverage Stage.
FOR LIS 3 Beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> No.
FOR LIS 4 Beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> Maybe. If you are in the Initial Coverage Limits Stage (ICL) or the Post-Initial Coverage Limits Stage of the benefit you will continue to pay your current coinsurance for RENVELA TABLETS

	<ul style="list-style-type: none">If you are in the Catastrophic Coverage Stage, you will continue to pay the LIS brand name copayment for RENVELA TABLETS.
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Log Activity

1003 – Plan Design Education

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Resolution Time

Information = immediate

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Related Documents

Grievance Standard Verbiage (for use in Discussion with Beneficiary) section in [MED D Care - Grievances in PeopleSafe and MedHOK](#)

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Parent SOP

CALL-0048: [Medicare Part D Customer Care Call Center Requirements-CVS Caremark Part D Services, L.L.C.](#)

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Abbreviations / Definitions

[Mail Service Customer Care Abbreviations and Definitions](#)

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EXHIBIT 30



P.O. Box 52431, Phoenix, AZ 85072-2431

September 24, 2018

[Redacted]
[Redacted] KY [Redacted]

**YOUR DRUG IS NOT ON OUR LIST OF COVERED DRUGS (FORMULARY)
OR IS SUBJECT TO CERTAIN LIMITS**

Dear [Redacted]:

We want to tell you that SilverScript Plus (PDP) has provided you with a temporary supply of the following prescription: SEVELAMER TAB 800MG.

This drug is either not included on our list of covered drugs (called our formulary), or it's included on the formulary but subject to certain limits, as described in more detail later in this letter. SilverScript Plus (PDP) is required to provide you with a temporary supply of this drug, as follows:

In the outpatient setting, we're required to provide a maximum of 30-day supply of medication. If your prescription is written for fewer days, we'll allow multiple fills to provide up to a maximum 30-day supply of medication.

It's important to understand that this is a temporary supply of this drug. Well before you run out of this drug, you should speak to SilverScript Plus (PDP) and/or the prescriber about:

- changing the drug to another drug that is on our formulary; or
- requesting approval for the drug by demonstrating that you meet our criteria for coverage; or
- requesting an exception from our criteria for coverage.

When you request approval for coverage or an exception from coverage criteria, these are called coverage determinations. Don't assume that any coverage determination, including any exception, you have requested or appealed has been approved just because you receive more fills of a drug. If we approve coverage, then we'll send you another written notice.

If you need assistance in requesting a coverage determination, including an exception, or if you want more information about when we will cover a temporary supply of a drug, contact us at 1-866-235-5660. TTY users should call 711. Live representatives are available 24 hours a day, 7 days a week. You can ask us for a coverage determination at any time. **Instructions on how to change your current prescription, how to ask for a coverage determination, including an exception, and how to appeal a denial if you disagree with our coverage determination are discussed at the end of this letter.**

The following is a specific explanation of why your drug is not covered or is limited.

Name of Drug: SEVELAMER TAB 800MG

Date Filled: 09/20/2018

Reason for Notification: This drug is not on our formulary. We will not continue to pay for this drug after you have received the maximum 30 days' temporary supply that we are required to cover unless you obtain a

formulary exception from us.

How do I change my prescription?

If your drug is not on our formulary, or is on our formulary, but we have placed a limit on it, then you can ask us what other drug used to treat your medical condition is on our formulary, ask us to approve coverage by showing that you meet our criteria, or ask us for an exception. We encourage you to ask your prescriber if this other drug that we cover is an option for you. You have the right to request an exception from us to cover your drug that was originally prescribed. If you ask for an exception, your prescriber will need to provide us with a statement explaining why a prior authorization, quantity limit, or other limit we have placed on your drug is not medically appropriate for you.

How do I request a coverage determination, including an exception?

You or your prescriber may contact us to request a coverage determination, including an exception. The toll-free phone number is 1-866-235-5660 (TTY users should call 711), or you may fax to 1-855-633-7673, or you may write to us at: SilverScript Insurance Company Prescription Drug Plans Coverage Decisions and Appeals Department, P.O. Box 52000, MC 109, Phoenix, AZ 85072-2000. We are available 24 hours a day, 7 days a week.

If you are requesting coverage of a drug that is not on our formulary, or an exception to a coverage rule, your prescriber must provide a statement supporting your request. It may be helpful to bring this notice with you to the prescriber or send a copy to his or her office. If the exception request involves a drug that is not on our formulary, the prescriber's statement must indicate that the requested drug is medically necessary for treating your condition because all of the drugs on our formulary would be less effective as the requested drug or would have adverse effects for you. If the exception request involves a prior authorization or other coverage rule we have placed on a drug that is on our formulary, the prescriber's statement must indicate that the coverage rule wouldn't be appropriate for you given your condition or would have adverse effects for you.

We must notify you of our decision no later than 24 hours, if the request has been expedited, or no later than 72 hours, if the request is a standard request, from when we receive your request. For exceptions, the timeframe begins when we obtain your prescriber's statement. Your request will be expedited if we determine, or your prescriber tells us, that your life, health, or ability to regain maximum function may be seriously jeopardized by waiting for a standard decision.

What if my request for coverage is denied?

If your request for coverage is denied, you have the right to appeal by asking for a review of the prior decision, which is called a redetermination. You must request this appeal within 60 calendar days from the date of our written decision on your coverage determination request. We accept standard and expedited requests by telephone and in writing. Contact us at: SilverScript Insurance Company Prescription Drug Plans Coverage Decisions and Appeals Department, P.O. Box 52000, MC 109, Phoenix, AZ 85072-2000; Phone: 1-866-235-5660; TTY: 711; Fax: 1-855-633-7673; 24 hours a day, 7 days a week.

If you need assistance in requesting a coverage determination, including an exception, or if you want more information about when we will cover a temporary supply of a drug, contact us at 1-866-235-5660, 24 hours a day, 7 days a week. TTY users should call 711. Live representatives are available 24 hours a day, 7 days a week. You can ask us for a coverage determination at any time. You can also visit our website at www.silverscript.com.

Sincerely,

SilverScript Plus (PDP)

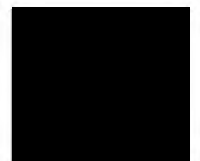
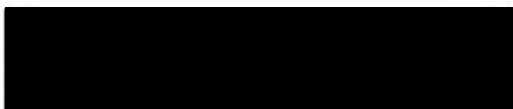
This information is not a complete description of benefits. Contact the plan for more information. Limitations, copayments, and restrictions may apply. Benefits, premium, and/or copayments/coinsurance may change on January 1 of each year.

The formulary may change at any time. You will receive notice when necessary.

Beneficiaries must use network pharmacies to access their prescription drug benefit.

ATTENTION: If you speak Spanish, language assistance services, free of charge, are available to you. Call 1-866-235-5660 (TTY: 711). ATENCIÓN: Si usted habla español, tenemos servicios de asistencia lingüística disponibles para usted sin costo alguno. Llame al 1-866-235-5660 (TTY: 711).

SilverScript is a Prescription Drug Plan with a Medicare contract offered by SilverScript Insurance Company. Enrollment in SilverScript depends on contract renewal.



ENGLISH

ATTENTION: If you speak English, language assistance services, free of charge, are available to you. Call 1-866-235-5660 (TTY: 711).

SPANISH

ATENCIÓN: Si usted habla español, tenemos servicios de asistencia lingüística disponibles para usted sin costo alguno. Llame al 1-866-235-5660 (TTY: 711).

CHINESE

***** 1-866-235-5660 (TTY: 711)*

VIETNAMESE

CHÚ Ý: Nếu quý vị nói tiếng Việt, thì có sẵn các dịch vụ trợ giúp ngôn ngữ miễn phí dành cho quý vị. Hãy gọi số 1-866-235-5660 (TTY: 711).

KOREAN

1-866-235-5660 (TTY: 711)* *****

TAGALOG

Pansinin: Kung nagsasalita ka ng Tagalog, mga serbisyo ng tulong sa wika, nang walang bayad, ay magagamit sa iyo. Tawagan ang 1-866-235-5660 (TTY: 711).

RUSSIAN

ВНИМАНИЕ: Если вы говорите на русском языке, вам будут бесплатно предоставлены услуги переводчика. Звоните по телефону: 1-866-235-5660 (телетайп: 711).

ARABIC

ملاحظة: إذا كنت تتحدث العربية، تتوفر خدمات المساعدة اللغوية مجاناً من أجلك. اتصل بالرقم 1-866-235-5660 (الهاتف النصي: 711).

FRENCH CREOLE

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 1-866-235-5660 (TTY: 711).

FRENCH

ATTENTION : Si vous parlez français, des services gratuits d'interprétation sont à votre disposition. Veuillez appeler le 1-866-235-5660 (TTY: 711).

POLISH

UWAGA: Dla osób mówiących po polsku dostępna jest bezpłatna pomoc językowa. Zadzwoń pod numer 1-866-235-5660 (TTY: 711).

PORTUGUESE

ATENÇÃO: Se fala português, estão disponíveis serviços gratuitos de assistência linguística na sua língua. Telefone para 1-866-235-5660 (TTY: 711).

ITALIAN

ATTENZIONE: Se lei parla italiano, sono disponibili servizi gratuiti di assistenza linguistica nella sua lingua. Chiami 1-866-235-5660 (TTY: 711).

JAPANESE

***** 1-866-235-5660 (TTY: 711)* *

GERMAN

BITTE BEACHTEN: Wenn Sie Deutsch sprechen, stehen Ihnen unsere Dolmetscher unter der Nummer 1-866-235-5660 (TTY: 711) kostenlos zur Verfügung.

FARSI

توجه: چنانچه به زبان فارسی صحبت میکنید، خدمات کمک زبانی، به صوتر اریگان، رد اختیار شما قرار خواهد گرفت. با شماره د: 1-866-235-5660 (TTY: 711) تماس بگیرید.

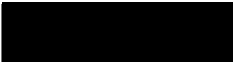


EXHIBIT 31



Notice of Approval of Medicare Prescription Drug Coverage

Date: 10/02/2018

[REDACTED]
[REDACTED] KY [REDACTED]

Member Name: [REDACTED]
Member ID Number: [REDACTED]

Thank you for trusting your Medicare prescription drug coverage to SilverScript Plus (PDP). As our member, we want to help you get the most value from your prescription drug coverage and help you understand how your coverage works.

As a member of SilverScript Plus (PDP), we are pleased to inform you that, upon review of the information provided by you or your doctor, we have approved the requested coverage for the following prescription drug(s):

SEVELAMER CARBONATE Tablet

Type of coverage approved: Non-Formulary

This approval authorizes your coverage from 09/01/2018 - 10/02/2019, unless we notify you otherwise, and as long as the following conditions apply:

- you remain enrolled in our Medicare Part D prescription drug plan,
- your physician or other prescriber continues to prescribe the medication for you, and
- the medication continues to be safe for treating your condition.

If you have not already filled your prescription for this approved drug, you may do so at a participating network pharmacy.

Thank you for allowing us to serve you. This letter is informational only. No further action is required by you at this time.

If you have questions or need help, please talk to your doctor or pharmacist, or contact Customer Care at 1-866-235-5660, 24 hours a day, 7 days a week. TTY users may call 711.

[REDACTED]

Thank you,

SilverScript Plus (PDP)

SilverScript is a Prescription Drug Plan with a Medicare contract offered by SilverScript Insurance Company. Enrollment in SilverScript depends on contract renewal.

EXHIBIT 32

Peoplesafe

Page 1 of 1

CAREMARK **PeopleSafe®** Close

Eligibility Maintenance ☐ Participant Inquiry ☐ Resolution Manager ☐ Medicare D Inquiry ☐ View Opportunities Tools: -- Select A Tool --

Client: **SILVERSCRIPT-INDIV-ENROLL** System: **RXCLAIM**

External ID: **[REDACTED]** Name: **[REDACTED]** Gndr: **M** Relationship: **MEMBER** Born: **[REDACTED] 1953** Effective: **11-01-2018** Expiration: **12-31-2039**

Navigation: [Main Screen](#) [Financial Details](#) [View Activity](#) [Prescription History](#) [Test Claims](#) [Plan Benefit Overview](#) [Account Balance](#) [Explanation of Benefits](#) [Transaction History](#) [Communication History](#) [Carmark.com](#)

Pharmacy Network: [Retail Transaction](#) [Plan Summary](#) [FSA/HSA/HRA History](#) [Coordination of Benefits](#) [Order Placement](#) [Adjustments](#) [Client Managed G & A](#) [View Triggers](#)

Prescription for: **[REDACTED] MEMBER** Delivery System: **POINT OF SALE** Dispense As Written: **0 - NO DAW**

Prescription Number: **[REDACTED]** [Go to Reimbursement...](#) Pharmacy NPI: **[REDACTED]** Drug Price Type: **AVERAGE WHOLESALE PRICE**

Drug NDC: **69097069393** Pharmacy NCPDP: **[REDACTED]** Drug Price Source: **MEDISPAN**

Drug Name: **SEVELAMEL CARBONATE** Pharmacy Name: **CVS PHARMACY [REDACTED]** Client Claim Price Type: **[REDACTED]** Pharmacy Claim Price Type: **[REDACTED]**

Participant Pay		Client Pay		Pharmacy Pay:	
Participant Copay:	119.80	Usual and Customary:		Usual and Customary:	
Initial Copay:	119.80	Cost Submitted:	398.80	Cost Allowed:	299.10
Gap Copay:	0.00	Cost Allowed:	299.10	Other Payer Recognized:	0.00
Catastrophic Copay:	0.00	Other Payer Recognized:	0.00	Dispensing Fee:	0.40
Network Penalty:	0.00	Dispensing Fee:	0.40	Level Of Effort Fee:	0.00
Deductible:	0.00	Level Of Effort Fee:	0.00	Administration Fee:	0.00
MAC / DAW Penalty:	0.00	Administration Fee:	0.00	Performance / Service Fee:	0.00
Non Formulary Penalty:	0.00	Performance / Service Fee:	0.00	Sales Tax:	0.00
After MAB:	0.00	Sales Tax:	0.00	PDP Service Fee:	0.00
- FSA Contribution Amount:	0.00	PRX Fee Amount:	0.00	Other Amount Paid:	0.00
- HRA Contribution Amount:	0.00	Client Billed Cost:	0.00		
+ COB Non Covered Amt:	0.00				
	=====	Total Client Cost:	179.70	Total Pharmacy Reimbursement:	179.70
Participant Cost:	119.80				

Health Reimbursement Account:		Miscellaneous	
Benefits:	0.00	Applied To Out of Pocket:	0.00
Member Access Fee:		Applied To TROOP:	0.00
Amount Used:	0.00	Applied To OOPM/MOOP:	0.00
HRA Remaining Balance:	0.00	Paid by Other Insurance:	0.00
		Alternate Amount Paid:	0.00
		Previous Amount Paid:	0.00
		In Network Accumulation:	0.00
		Out of Network Accumulation:	0.00

Med D Financials:	
LICS Paid by Plan:	0.00
SPAP/Integrator Paid Amt:	0.00
Reported Gap Discount:	0.00
Deductible Gross Cost:	0.00
Deductible Plan Pay:	0.00
Initial Gross Cost:	299.50
Initial Plan Pay:	179.70
Gap Gross Cost:	0.00
Gap Plan Pay:	0.00
Catastrophic Gross Cost:	0.00
Catastrophic Plan Pay:	0.00

[View Settlement Codes](#) [View Comments](#) [Back](#)

Pharmacy Reimbursement

Reimbursement Type:
Reimbursement Number:
Reimbursement Amount:
Posting Date:
Reporting Number:

Reversal

Reimbursement Type:
Reimbursement Number:
Reimbursement Amount:
Posting Date:
Reporting Number:

[View Reimbursements](#)

Recipient

Name:
Alternate Name:
Address:
City:
State:
Zip:

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EXHIBIT 33

Peoplesafe

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CAREMARK
Peoplesafe®
Close

[Eligibility Maintenance](#)
[Participant Inquiry](#)
[Resolution Manager](#)
[Medicare Inquiry](#)

View Opportunities

Tools:
-- Select A Tool --

Client: SILVERSCRIPT-INDIV-ENROLL **System:** RXCLAIM
External ID: **Name:** **Gndr:** M **Relationship:** MEMBER **Born:** 953 **Effective:** 11-01-2018 **Expiration:** 12-31-2039

[Main Screen](#)
[Financial Details](#)
[View Activity](#)
[Prescription History](#)
[Test Claims](#)
[Plan Benefit Overview](#)
[Account Balance](#)
[Explanation of Benefits](#)
[Transaction History](#)
[Communication History](#)
[CAREMARK.com](#)

[Pharmacy Network](#)
[Retail Transaction](#)
[Plan Summary](#)
[FSA/HSA/HRA History](#)
[Coordination of Benefits](#)
[Order Placement](#)
[Adjustments](#)
[Client Managed \(G & A\)](#)
[View Triggers](#)

Prescription for: MEMBER **Delivery System:** POINT OF SALE
Prescription Number: [Go to Reimbursement...](#) **Pharmacy NPI:** **Pharmacy Name:** CVS PHARMACY
Drug NDC: 58468013001 **Pharmacy NCPDP:** **Drug Price Source:** 1 - PHYSICIAN DAW
Drug Name: RENVELLA **Pharmacy Claim Price Type:** AVERAGE WHOLESALE PRICE
MEDISPAN

Participant Pay

Participant Copay:	35.00
Initial Copay:	35.00
Gap Copay:	0.00
Catastrophic Copay:	0.00
Network Penalty:	0.00
Deductible:	0.00
MAC / DAW Penalty:	0.00
Non Formulary Penalty:	0.00
After MAB:	0.00
- FSA Contribution Amount:	0.00
- HRA Contribution Amount:	0.00
+ COB Non Covered Amt:	0.00
Participant Cost:	35.00

Client Pay

Usual and Customary:	
Cost Submitted:	1219.21
Cost Allowed:	1024.14
Other Payer Recognized:	0.00
Dispensing Fee:	0.40
Level Of Effort Fee:	0.00
Administration Fee:	0.00
Performance / Service Fee:	0.00
Sales Tax:	0.00
PRX Fee Amount:	0.00
Client Billed Cost:	0.00
Total Client Cost:	999.54

Pharmacy Pay:

Usual and Customary:	
Cost Allowed:	1024.14
Other Payer Recognized:	0.00
Dispensing Fee:	0.40
Level Of Effort Fee:	0.00
Administration Fee:	0.00
Performance / Service Fee:	0.00
Sales Tax:	0.00
PDP Service Fee:	0.00
Other Amount Paid:	0.00
Total Pharmacy Reimbursement:	989.54

Health Reimbursement Account:

Benefits:	0.00
Member Access Fee:	
Amount Used:	0.00
HRA Remaining Balance:	0.00

Miscellaneous

Applied To Out of Pocket:	0.00
Applied To TROOP:	0.00
Applied To OOPM/MOOP:	0.00
Paid by Other Insurance:	0.00
Alternate Amount Paid:	0.00
Previous Amount Paid:	0.00
In Network Accumulation:	0.00
Out of Network Accumulation:	0.00

Med D Financials:

LICS Paid by Plan:	0.00
SPAP/Integrator Paid Amt:	0.00
Reported Gap Discount:	0.00
Deductible Gross Cost:	0.00
Deductible Plan Pay:	0.00
Initial Gross Cost:	1024.54
Initial Plan Pay:	989.54
Gap Gross Cost:	0.00
Gap Plan Pay:	0.00
Catastrophic Gross Cost:	0.00
Catastrophic Plan Pay:	0.00

[View Settlement Codes](#)
[View Comments](#)

[Back](#)

Pharmacy Reimbursement

Reimbursement Type:
Reimbursement Number:
Reimbursement Amount:
Posting Date:
Reporting Number:

Recipient

Name:
Alternate Name:
Address:
City:
State:
Zip:

Reversal
Reimbursement Type:
Reimbursement Number:
Reimbursement Amount:
Posting Date:
Reporting Number:
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EXHIBIT 34

MED D - EPCLUSA® TABLETS Generic Not Available for SilverScript Choice, Plus, and Allure (PDP) Plans Until Further Notice <Document_Number>

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[Background](#)

[Rationale](#)

[What does this mean for the beneficiary?](#)

[Effects of this Strategy on Beneficiaries](#)

[FAQs](#)

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Grievance Standard Verbiage:

Grievance Standard Verbiage (for use in Discussion with Beneficiary) section in [MED D Care - Grievances in PeopleSafe and MedHOK](#)

Legend:

Icon	Explanation
	Updates to information. The icon should be followed by the date of update. Note: Only the last update will be identified.
	Indicates Important or Urgent information
	Indicates a Talk Track

Overview

EPCLUSA® TABLETS is a branded prescription drug commonly used for the treatment of chronic infection of Hepatitis C. This prescription drug was recently launched in its generic form, sofosbuvir/velpatasvir 400MG-100MG tablets. The generic form of EPCLUSA TABLETS is not available on SilverScript Choice, Plus, or Allure (PDP) plans until further notice.

EPCLUSA® TABLETS will be MAINTAINED on the Specialty Tier (Tier 5) in 2018 and 2019 on the formularies for SilverScript Choice, Plus, and Allure beneficiaries. The generic, sofosbuvir/velpatasvir 400MG-100MG tablets, will **not** be added to the formularies.

This applies only to SilverScript Choice and Plus beneficiaries in 2018 and SilverScript Choice, Plus, and Allure beneficiaries in 2019.

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Background

Generic prescription drugs are typically the lowest-cost option when compared to branded prescription drugs. SilverScript **promotes the use of generic prescription drugs** to help plan beneficiaries save money.

- During the initial launch phase for the generic, there will be few manufacturers marketing the generic and the cost of the generic is expected to be relatively high.
- To help keep out-of-pocket costs low, SilverScript is retaining brand EPCLUSA® TABLETS on its formulary on Specialty Tier (Tier 5). EPCLUSA is eligible for a manufacturer discount in the coverage gap.
- SilverScript will continue to keep the brand version of EPCLUSA TABLETS on the formulary and will **NOT** be adding the generic version until further notice.

Network Pharmacies were also informed of this update.



NOTE: SilverScript Employer PDP Plans are being handled differently.

- **SilverScript Choice, Plus, and Allure Plans**

The generic version of EPCLUSA TABLETS (sofosbuvir/velpatasvir 400MG-100MG tablets) will **NOT** be added to the SilverScript formularies for SilverScript Choice and Plus in 2018 and Choice, Plus, and Allure plans in 2019.

- **SilverScript Employer PDP Plans**

Employer PDP Plans have added the generic (sofosbuvir/velpatasvir 400MG-100MG tablets) to their formulary for 2018 and 2019. Some plans will continue cover the brand in 2018 and 2019.

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Rationale

The goal of this document is to prepare the MED D Customer Care Representative (CCR) for potential inbound questions from the beneficiary regarding the availability of sofosbuvir/velpatasvir 400MG-100MG tablets and the non-covered status for this prescription drug on SilverScript Plans.

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What does this mean for the beneficiary?



Retaining brand EPCLUSA TABLETS on Specialty Tier (Tier 5) can help keep out-of-pocket costs low for SilverScript beneficiaries.

NOTE: The generic equivalent sofosbuvir/velpatasvir 400MG-100MG tablets is **not** be on the formulary until further notice.

- Beneficiaries have the option to request an exception if they wish to obtain sofosbuvir/velpatasvir 400MG-100MG tablets.
 - However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.
- Brand EPCLUSA TABLETS is available at the Specialty Tier (Tier 5) copay/coinsurance, so if the request for the generic is granted, the beneficiary would pay the amount associated with the plan's exception tier. This may be a different cost than the brand.

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Effects of this Strategy on Beneficiaries










- Beneficiaries will continue to receive the brand EPCLUSA TABLETS at the Specialty Tier (Tier 5) cost share.
- The CCR may receive calls from MED D beneficiaries who are confused about the lack of generic version availability of the prescription drug. Refer to the [FAQs](#) section of this document for appropriate responses.


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FAQs

The frequently asked questions below will assist the CCR when addressing incoming calls regarding EPCLUSA TABLETS.



NOTE: These specifics apply to non-LIS beneficiaries. See specific Q&A at end of this FAQ section for LIS-specific information.





Question	Answer		
<p>Will EPCLUSA TABLETS cost more than sofosbuvir/velpatasvir 400MG-100MG tablets in any stage of the Medicare D benefit for non-LIS beneficiaries?</p>	<p>SAY:</p> <ul style="list-style-type: none"> This will vary based on your Plan and which Medicare Part D coverage stage you currently are in (e.g., Deductible, Initial Coverage Limits, Coverage Gap or Catastrophic). <p>CCR Process Note: The CCR will review the following grid for information on the anticipated costs of EPCLUSA TABLETS vs. sofosbuvir/velpatasvir 400MG-100MG tablets during the sofosbuvir/velpatasvir 400MG-100MG tablets initial launch period:</p> <table border="1"> <tr> <td data-bbox="717 622 1044 1225"> <p>Deductible Stage for non-LIS beneficiaries:</p> </td><td data-bbox="1044 622 1713 1225"> <p> SilverScript Choice , Plus, and Allure beneficiaries:</p> <ul style="list-style-type: none">  In 2018, no deductible, except for Choice Plan beneficiaries residing in Alaska who will have a \$405 annual deductible and Choice Plan beneficiaries residing in Arizona and Hawaii who will have a \$100 annual deductible for drugs in Tiers 3 to 5. Plus Plan is not available in Alaska. Allure Plan not available in 2018.  In 2019, no deductible except for Choice Plan beneficiaries who will have a \$100 annual deductible for drugs in Tiers 3 to 5 for beneficiaries residing in Colorado, Georgia, or Texas; Choice beneficiaries residing in Arizona, South Carolina, or Alaska will have a \$415 deductible for drugs in Tiers 3 to 5. </td></tr> </table>	<p>Deductible Stage for non-LIS beneficiaries:</p>	<p> SilverScript Choice , Plus, and Allure beneficiaries:</p> <ul style="list-style-type: none">  In 2018, no deductible, except for Choice Plan beneficiaries residing in Alaska who will have a \$405 annual deductible and Choice Plan beneficiaries residing in Arizona and Hawaii who will have a \$100 annual deductible for drugs in Tiers 3 to 5. Plus Plan is not available in Alaska. Allure Plan not available in 2018.  In 2019, no deductible except for Choice Plan beneficiaries who will have a \$100 annual deductible for drugs in Tiers 3 to 5 for beneficiaries residing in Colorado, Georgia, or Texas; Choice beneficiaries residing in Arizona, South Carolina, or Alaska will have a \$415 deductible for drugs in Tiers 3 to 5.
<p>Deductible Stage for non-LIS beneficiaries:</p>	<p> SilverScript Choice , Plus, and Allure beneficiaries:</p> <ul style="list-style-type: none">  In 2018, no deductible, except for Choice Plan beneficiaries residing in Alaska who will have a \$405 annual deductible and Choice Plan beneficiaries residing in Arizona and Hawaii who will have a \$100 annual deductible for drugs in Tiers 3 to 5. Plus Plan is not available in Alaska. Allure Plan not available in 2018.  In 2019, no deductible except for Choice Plan beneficiaries who will have a \$100 annual deductible for drugs in Tiers 3 to 5 for beneficiaries residing in Colorado, Georgia, or Texas; Choice beneficiaries residing in Arizona, South Carolina, or Alaska will have a \$415 deductible for drugs in Tiers 3 to 5. 		



		<ul style="list-style-type: none"> SilverScript Plus and Allure Plans are not available in Alaska. <p>Move to response below in Initial Coverage Limits Stage.</p>
	Initial Coverage Limits (ICL) Stage for non-LIS beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> Maybe. You will continue to pay your current Specialty Tier (Tier 5) cost share during the Initial Coverage Limits stage for brand EPCLUSA TABLETS. Mr. /Mrs. <Beneficiary>, your cost share for brand EPCLUSA TABLETS will be <\$X.XX>. <p>Move to response below in Coverage Gap Stage.</p>
	Coverage Gap Stage for non-LIS beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> No. The Coverage Gap Stage (also called the donut hole) is where you will receive significant savings on brand EPCLUSA TABLETS. The brand name is less expensive than the generic version because of the manufacturer discount on brand name prescription drugs.  In 2018, your cost share in the Coverage Gap Stage is 35% of the price of

		<ul style="list-style-type: none"> • brand EPCLUSA TABLETS. If the generic were included at this time on the formulary, your cost share would be 44%. • 🚩 In 2019, your cost share in the Coverage Gap Stage is 25% of the price of brand EPCLUSA TABLETS. If the generic were included at this time on the formulary, your cost share would be 37%. <p>Move to response below in Catastrophic Coverage Stage.</p>
	Catastrophic Stage for non-LIS beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> • Yes. • 🚩 During this stage of the benefit, it is expected that - because of the price of the brand and generic versions - you will pay 5% of the allowed cost.
Why is the brand-name EPCLUSA TABLETS on the formulary when there is now a generic available?	<p>SAY:</p> <ul style="list-style-type: none"> • 🚩 In this case, the price of the generic version of EPCLUSA TABLETS will likely be similar to the price of the brand version for a minimum of six months, and perhaps longer. • 🚩 There are few manufacturers of the generic version of EPCLUSA TABLETS to drive the price down. • 	

	<ul style="list-style-type: none"> Until there are competitors and the price of the generic version goes down, your plan will continue to cover brand-name EPCLUSA TABLETS at the Specialty Tier (Tier 5) cost share in 2018 and 2019.
Why can't I get the generic? Aren't generics less expensive?	<p>SAY:</p> <ul style="list-style-type: none"> When a generic version is first available, it is typically similar in price to the brand version. At this time the generic version, called sofosbuvir/velpatasvir 400MG-100MG tablets, is not on the formulary. <ul style="list-style-type: none"> You do have the option to request a formulary exception. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.
Will my other copays for other prescription drugs be lowered?	<p>SAY:</p> <ul style="list-style-type: none"> No. You will continue to pay the copay/coinsurance for other brand name and generic prescription drugs at the current benefit copay.
Could there be other brand prescription drugs that this applies to?	<p>SAY:</p> <ul style="list-style-type: none"> In most cases the generic version of a prescription drug is less expensive than the brand name version and is covered at the lower generic copay. The exception typically applies during the first few years the generic version of a prescription drug is launched.
How long will EPCLUSA	SAY:

<p>TABLETS remain on the formulary on the Specialty Tier (Tier 5)?</p>	<ul style="list-style-type: none"> •  We anticipate that EPCLUSA TABLETS will remain on the formulary on the Specialty Tier (Tier 5) in 2018 and 2019 until the price of the generic form of EPCLUSA TABLETS drops. •  We anticipate it will be a minimum of six months, however that is based on market conditions not within our control and could change.
<p>What should I do if brand EPCLUSA TABLETS is removed from the formulary during the plan year?</p>	<p>SAY:</p> <ul style="list-style-type: none"> • We will provide you with prior notification if brand EPCLUSA TABLETS removed from the formulary during the Plan year. • The type of notification depends on whether you are taking the prescription drug and whether the change happens during the plan year or at the beginning of the next plan year. <ul style="list-style-type: none"> ◦ If we make this change during the plan year, and you are taking EPCLUSA TABLETS, you will receive written notification in your Explanation of Benefits (EOB). ◦ If we make this change at the beginning of the next plan year, the change will be noted in the formulary included as part of your Annual Notice of Change (ANOC) packet. ◦ You should review your plan's formulary carefully. • If brand EPCLUSA TABLETS is removed from the formulary and you want to continue taking brand EPCLUSA TABLETS, you will have the option to request a formulary exception. • However, exception requests for non-formulary prescription drugs, if

	<ul style="list-style-type: none"> approved, are typically approved for coverage at the highest cost share level. 	
May I, as the beneficiary, request a coverage determination for the generic product?	<p>SAY:</p> <ul style="list-style-type: none"> Yes, you as the beneficiary may request a coverage determination for sofosbuvir/velpatasvir 400MG-100MG tablets. <ul style="list-style-type: none"> However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level. <p> Refer to the Med D Care - Coverage Determination/Appeal (New or Status Update) document.</p>	
Will sofosbuvir/velpatasvir 400MG-100MG tablets be added to the formulary during the 2019 plan year?	<p>SAY:</p> <p>The addition of the generic to the formulary will be re-evaluated during the year.</p>	
<p> Will EPCLUSA TABLETS cost more than sofosbuvir/velpatasvir 400MG-100MG tablets in any stage of the Medicare Part D benefit for LIS beneficiaries?</p>	<p> CCR Process Note: The CCR will review the following information for LIS beneficiaries on the anticipated costs of EPCLUSA TABLETS vs. sofosbuvir/velpatasvir 400MG-100MG tablets during the sofosbuvir/velpatasvir 400MG-100MG tablets initial launch period:</p>	
	<p> For LIS 1 & 2 Beneficiaries:</p>	<p>SAY:</p> <ul style="list-style-type: none"> Maybe. In the Catastrophic Coverage Stage of the benefit, you will continue to receive EPCLUSA TABLETS at no cost. If you have not yet reached the Catastrophic Coverage Stage, you might have to pay your brand name copayment for EPCLUSA TABLETS until you reach the Catastrophic Coverage

		<ul style="list-style-type: none"> • Stage.
	 FOR LIS 3 Beneficiaries:	SAY: <ul style="list-style-type: none"> • No.
	 FOR LIS 4 Beneficiaries:	SAY: <ul style="list-style-type: none"> • Maybe. • If you are in the Initial Coverage Limits Stage (ICL) or the Post-Initial Coverage Limits Stage of the benefit you will continue to pay your current coinsurance for EPCLUSA TABLETS. • If you are in the Catastrophic Coverage Stage, you will continue to pay the LIS brand-name copayment for EPCLUSA TABLETS.

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Log Activity

1003 – Plan Design Education

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Resolution Time

Information = immediate

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Parent SOP

CALL-0048: Medicare Part D Customer Care Call Center Requirements- CVS Caremark Part D Services, L.L.C.

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ELECTRONIC DATA = OFFICIAL VERSION – PAPER COPY – INFORMATIONAL ONLY

EXHIBIT 35

MED D - HARVONI® TABLETS Generic Not Available for SilverScript Choice, Plus, and Allure (PDP) Plans Until Further Notice

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[Background](#)

[What does this mean for the beneficiary?](#)

[Effects of this Strategy on Beneficiaries](#)

[FAQs](#)

[Log Activity](#)

[Resolution Time](#)

[Related Documents](#)

[Parent SOP](#)

[Abbreviations / Definitions](#)

Overview

HARVONI® TABLETS is a branded prescription drug commonly used for the treatment of Hepatitis C. This prescription drug was recently launched in its generic form, ledipasvir/sofosbuvir 90MG-400 MG tablets. The generic form of HARVONI TABLETS is not available on SilverScript Choice, Plus, or Allure (PDP) plans until further notice.

HARVONI® TABLETS will be MAINTAINED on the Specialty Tier (Tier 5) in 2019 on the formularies for SilverScript Choice, Plus, and Allure beneficiaries. The generic, ledipasvir/sofosbuvir 90MG-400 MG tablets, will **not** be added to the formularies.

This applies to SilverScript Choice, Plus, and Allure beneficiaries in 2019.

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Background

Generic prescription drugs are typically the lowest-cost option when compared to branded prescription drugs. SilverScript **promotes the use of generic prescription drugs** to help plan beneficiaries save money.

- During the initial launch phase for the generic, there will be few manufacturers marketing the generic and the cost of the generic is expected to be relatively high.
- To help keep out-of-pocket costs low, SilverScript is retaining brand HARVONI® TABLETS on its formulary on Specialty Tier (Tier 5). HARVONI is eligible for a manufacturer discount in the coverage gap.
- SilverScript will continue to keep the brand version of HARVONI TABLETS on the formulary and will **NOT** be adding the generic version until further notice.

Network Pharmacies were also informed of this update.

Note: SilverScript Employer PDP Plans are being handled differently.

- **SilverScript Choice, Plus, and Allure Plans**

The generic version of HARVONI TABLETS (ledipasvir/sofosbuvir 90MG-400 MG tablets) will **NOT** be added to the SilverScript formularies for SilverScript Choice, Plus, and Allure plans in 2019.

- **SilverScript Employer PDP Plans**

Employer PDP Plans have added the generic (ledipasvir/sofosbuvir 90MG-400 MG tablets) to their formulary for 2019. Some plans will continue cover the brand in 2019.

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What does this mean for the beneficiary?

Retaining brand HARVONI TABLETS on Specialty Tier (Tier 5) can help keep out-of-pocket costs low for SilverScript beneficiaries.

NOTE: The generic equivalent ledipasvir/sofosbuvir 90MG-400 MG tablets is **not** be on the formulary until further notice.

- Beneficiaries have the option to request an exception if they wish to obtain ledipasvir/sofosbuvir 90MG-400 MG tablets.
 - However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.
- Brand HARVONI TABLETS is available at the Specialty Tier (Tier 5) copay/coinsurance, so if the request for the generic is granted, the beneficiary would pay the amount associated with the plan's exception tier. This may be a different cost than the brand.

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Effects of this Strategy on Beneficiaries

- Beneficiaries will continue to receive the brand HARVONI TABLETS at the Specialty Tier (Tier 5) cost share.
- The CCR may receive calls from MED D beneficiaries who are confused about the lack of generic version availability of the prescription drug. Refer to the [FAQs](#) section of this document for appropriate responses.

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FAQs

The frequently asked questions below will assist the CCR when addressing incoming calls regarding HARVONI TABLETS.


Note: These specifics apply to non-LIS beneficiaries. See specific Q&A at end of this FAQ section for LIS-specific information.

Question	Answer	
Will HARVONI TABLETS cost more than ledipasvir/sofosbuvir 90MG-400 MG tablets in any stage of the Medicare D benefit for non-LIS beneficiaries?	SAY: <ul style="list-style-type: none"> This will vary based on your Plan and which Medicare Part D coverage stage you currently are in (e.g., Deductible, Initial Coverage Limits, Coverage Gap or Catastrophic). CCR Process Note: The CCR will review the following grid for information on the anticipated costs of HARVONI TABLETS vs. ledipasvir/sofosbuvir 90MG-400 MG tablets during the ledipasvir/sofosbuvir 90MG-400 MG tablets initial launch period:	
	Deductible Stage for non-LIS beneficiaries:	SilverScript Choice , Plus, and Allure beneficiaries: <ul style="list-style-type: none"> In 2019, no deductible except for Choice Plan beneficiaries who will have a \$100 annual deductible for drugs in Tiers 3 to 5 for beneficiaries residing in Colorado, Georgia, or Texas; Choice beneficiaries residing in Arizona and South Carolina will have a \$100 annual deductible for drugs in Tiers 3 to 5, or Alaska will have a \$415 deductible for all drugs. SilverScript Plus and Allure Plans do not have a deductible.

		Move to response below in Initial Coverage Limits Stage.
	Initial Coverage Limits (ICL) Stage for non-LIS beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> • Maybe. • You will continue to pay your current Specialty Tier (Tier 5) cost share during the Initial Coverage Limits stage for brand HARVONI TABLETS. • Mr. /Mrs. <Beneficiary>, your cost share for brand HARVONI TABLETS will be <\$X.XX>. <p>Move to response below in Coverage Gap Stage.</p>
	Coverage Gap Stage for non-LIS beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> • No. • The Coverage Gap Stage (also called the donut hole) is where you will receive significant savings on brand HARVONI TABLETS. • The brand name is less expensive than the generic version because of the manufacturer discount on brand name prescription drugs. • • In 2019, your cost share in the Coverage Gap Stage is 25% of the price of brand HARVONI TABLETS. If the generic were included at this time on the formulary, your cost share would be 37%.

		Move to response below in Catastrophic Coverage Stage.
	Catastrophic Stage for non-LIS beneficiaries:	SAY: <ul style="list-style-type: none"> • Yes. • During this stage of the benefit, it is expected that - because of the price of the brand and generic versions - you will pay 5% of the allowed cost.
Why is the brand-name HARVONI TABLETS on the formulary when there is now a generic available?	SAY: <ul style="list-style-type: none"> • In this case, the price of the generic version of HARVONI TABLETS will likely be similar to the price of the brand version for a minimum of six months, and perhaps longer. • There are few manufacturers of the generic version of HARVONI TABLETS to drive the price down. • Until there are competitors and the price of the generic version goes down, your plan will continue to cover brand-name HARVONI TABLETS at the Specialty Tier (Tier 5) cost share in 2019. 	
Why can't I get the generic? Aren't generics less expensive?	SAY: <ul style="list-style-type: none"> • When a generic version is first available, it is typically similar in price to the brand version. • At this time the generic version, called ledipasvir/sofosbuvir 90MG-400 MG tablets, is not on the formulary. <ul style="list-style-type: none"> ○ You do have the option to request a formulary exception. ○ However, exception requests for non-formulary prescription drugs, 	

	<ul style="list-style-type: none"> o f approved, are typically approved for coverage at the highest cost share level.
Will my other copays for other prescription drugs be lowered?	SAY: <ul style="list-style-type: none"> • No. • You will continue to pay the copay/coinsurance for other brand name and generic prescription drugs at the current benefit copay.
Could there be other brand prescription drugs that this applies to?	SAY: <ul style="list-style-type: none"> • In most cases the generic version of a prescription drug is less expensive than the brand name version and is covered at the lower generic copay. • The exception typically applies during the first few years the generic version of a prescription drug is launched.
How long will HARVONI TABLETS remain on the formulary on the Specialty Tier (Tier 5)?	SAY: <ul style="list-style-type: none"> • We anticipate that HARVONI TABLETS will remain on the formulary on the Specialty Tier (Tier 5) in 2019 until the price of the generic form of HARVONI TABLETS drops. • We anticipate it will be a minimum of six months, however that is based on market conditions not within our control and could change.
What should I do if brand HARVONI TABLETS is removed from the formulary during the plan year?	SAY: <ul style="list-style-type: none"> • We will provide you with prior notification if brand HARVONI TABLETS removed from the formulary during the Plan year. • The type of notification depends on whether you are taking the prescription drug and whether the change happens during the plan year or at the beginning of the next plan year.

	<ul style="list-style-type: none"> ○ If we make this change during the plan year, and you are taking HARVONI TABLETS, you will receive written notification in your Explanation of Benefits (EOB). ○ If we make this change at the beginning of the next plan year, the change will be noted in the formulary included as part of your Annual Notice of Change (ANOC) packet. ○ You should review your plan's formulary carefully. • If brand HARVONI TABLETS is removed from the formulary and you want to continue taking brand HARVONI TABLETS, you will have the option to request a formulary exception. • However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.
May I, as the beneficiary, request a coverage determination for the generic product?	<p>SAY:</p> <ul style="list-style-type: none"> • Yes, you as the beneficiary may request a coverage determination for ledipasvir/sofosbuvir 90MG-400 MG tablets. <ul style="list-style-type: none"> ○ However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level. <p> Refer to the Med D Care - Coverage Determination/Appeal (New or Status Update) document.</p>
Will ledipasvir/sofosbuvir 90MG-400 MG tablets be added to the formulary	<p>SAY:</p> <p>The addition of the generic to the formulary will be re-evaluated during the year.</p>

during the 2019 plan year?							
Will HARVONI TABLETS cost more than ledipasvir/sofosbuvir 90MG-400 MG tablets in any stage of the Medicare Part D benefit for LIS beneficiaries?	<p>CCR Process Note: The CCR will review the following information for LIS beneficiaries on the anticipated costs of HARVONI TABLETS vs. ledipasvir/sofosbuvir 90MG-400 MG tablets during the ledipasvir/sofosbuvir 90MG-400 MG tablets initial launch period:</p>						
	<table border="1"> <tr> <td data-bbox="723 471 1044 771">For LIS 1 & 2 Beneficiaries:</td><td data-bbox="1044 471 1721 771"> <p>SAY:</p> <ul style="list-style-type: none"> • Maybe. • In the Catastrophic Coverage Stage of the benefit, you will continue to receive HARVONI TABLETS at no cost. • If you have not yet reached the Catastrophic Coverage Stage, you might have to pay your brand name copayment for HARVONI TABLETS until you reach the Catastrophic Coverage Stage. </td></tr> <tr> <td data-bbox="723 779 1044 871">FOR LIS 3 Beneficiaries:</td><td data-bbox="1044 779 1721 871"> <p>SAY:</p> <ul style="list-style-type: none"> • No. </td></tr> <tr> <td data-bbox="723 871 1044 1175">FOR LIS 4 Beneficiaries:</td><td data-bbox="1044 871 1721 1175"> <p>SAY:</p> <ul style="list-style-type: none"> • Maybe. • If you are in the Initial Coverage Limits Stage (ICL) or the Post-Initial Coverage Limits Stage of the benefit you will continue to pay your current coinsurance for HARVONI TABLETS. • If you are in the Catastrophic Coverage Stage, you will continue to pay the LIS brand-name copayment for HARVONI TABLETS. </td></tr> </table>	For LIS 1 & 2 Beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> • Maybe. • In the Catastrophic Coverage Stage of the benefit, you will continue to receive HARVONI TABLETS at no cost. • If you have not yet reached the Catastrophic Coverage Stage, you might have to pay your brand name copayment for HARVONI TABLETS until you reach the Catastrophic Coverage Stage. 	FOR LIS 3 Beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> • No. 	FOR LIS 4 Beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> • Maybe. • If you are in the Initial Coverage Limits Stage (ICL) or the Post-Initial Coverage Limits Stage of the benefit you will continue to pay your current coinsurance for HARVONI TABLETS. • If you are in the Catastrophic Coverage Stage, you will continue to pay the LIS brand-name copayment for HARVONI TABLETS.
For LIS 1 & 2 Beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> • Maybe. • In the Catastrophic Coverage Stage of the benefit, you will continue to receive HARVONI TABLETS at no cost. • If you have not yet reached the Catastrophic Coverage Stage, you might have to pay your brand name copayment for HARVONI TABLETS until you reach the Catastrophic Coverage Stage. 						
FOR LIS 3 Beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> • No. 						
FOR LIS 4 Beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> • Maybe. • If you are in the Initial Coverage Limits Stage (ICL) or the Post-Initial Coverage Limits Stage of the benefit you will continue to pay your current coinsurance for HARVONI TABLETS. • If you are in the Catastrophic Coverage Stage, you will continue to pay the LIS brand-name copayment for HARVONI TABLETS. 						

[Top of the Document](#)

Log Activity

1003 – Plan Design Education

[Top of the Document](#)

Resolution Time

Information = immediate

[Top of the Document](#)

Related Documents

Grievance Standard Verbiage (for use in Discussion with Beneficiary) section in [MED D Care - Grievances in PeopleSafe and MedHOK](#)

[Top of the Document](#)

Parent SOP

CALL-0048: [Medicare Part D Customer Care Call Center Requirements-CVS Caremark Part D Services, L.L.C.](#)

[Top of the Document](#)

Abbreviations / Definitions

[Mail Service Customer Care Abbreviations and Definitions](#)

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EXHIBIT 36

Peoplesafe

Page 1 of 1

CAREMARK **PeopleSafe®** Close

Eligibility Maintenance ☐ Participant Inquiry ☐ Resolution Manager ☐ Medicare Inquiry ☐ View Opportunities Tools: -- Select A Tool --

Client: **SILVERSCRIPT-INDIV-ENROLL** System: **RXCLAIM**

External ID: **[REDACTED]** Name: **[REDACTED]** Gndr: **M** Relationship: **MEMBER** Born: **[REDACTED] 1953** Effective: **01-01-2019** Expiration: **12-31-2039**

[Main Screen](#) [Financial Details](#) [View Activity](#) [Prescription History](#) [Test Claims](#) [Plan Benefit Overview](#) [Account Balance](#) [Explanation of Benefits](#) [Transaction History](#) [Communication History](#) [Caremark.com](#)

[Pharmacy Network](#) [Retail Transaction](#) [Plan Summary](#) [FSA/HSA/HRA History](#) [Coordination of Benefits](#) [Order Placement](#) [Adjustments](#) [Client Managed \(G & A\)](#) [View Triggers](#)

Prescription for: **[REDACTED] MEMBER** Delivery System: **POINT OF SALE** Dispense As Written: **0 - NO DAW**
 Prescription Number: **[REDACTED]** [Go to Reimbursement...](#) Pharmacy NPI: **[REDACTED]** Drug Price Type: **AVERAGE WHOLESALE PRICE**
 Drug NDC: **[REDACTED]** Pharmacy NCPDP: **[REDACTED]** Drug Price Source: **MEDISPAN**
 Drug Name: **SCFOSBUWIR-VELPATASVIR** Pharmacy Name: **VALMART PHARMACY** Pharmacy Claim Price Type:

Participant Pay		Client Pay		Pharmacy Pay:	
Participant Copay:	2790.46	Usual and Customary:		Usual and Customary:	
Initial Copay:	1906.13	Cost Submitted:	9600.00	Cost Allowed:	8083.20
Gap Copay:	838.45	Cost Allowed:	8083.20	Other Payer Recognized:	0.00
Catastrophic Copay:	45.88	Other Payer Recognized:	0.00	Dispensing Fee:	0.50
Network Penalty:	0.00	Dispensing Fee:	0.50	Level Of Effort Fee:	0.00
Deductible:	0.00	Level Of Effort Fee:	0.00	Administration Fee:	0.00
MAC / DAW Penalty:	0.00	Administration Fee:	0.00	Performance / Service Fee:	0.00
Non Formulary Penalty:	0.00	Performance / Service Fee:	0.00	Sales Tax:	0.00
After MAB:	0.00	Sales Tax:	0.00	PDP Service Fee:	0.00
- FSA Contribution Amount:	0.00	PRX Fee Amount:	0.00	Other Amount Paid:	0.00
- HRA Contribution Amount:	0.00	Client Billed Cost:	0.00		
+ COB Non Covered Amt:	0.00				
	=====	Total Client Cost:	5293.24	Total Pharmacy Reimbursement:	5293.24
Participant Cost:	2790.46				

Health Reimbursement Account:		Miscellaneous	
Benefits:	0.00	Applied To Out of Pocket:	0.00
Member Access Fee:		Applied To TROOP:	0.00
Amount Used:	0.00	Applied To OOPM/MOOP:	0.00
HRA Remaining Balance:	0.00	Paid by Other Insurance:	0.00
		Alternate Amount Paid:	0.00
		Previous Amount Paid:	0.00
		In Network Accumulation:	0.00
		Out of Network Accumulation:	0.00

Med D Financials:	
LICS Paid by Plan:	0.00
SPAP/Integrator Paid Amt:	0.00
Reported Gap Discount:	2347.68
Deductible Gross Cost:	0.00
Deductible Plan Pay:	0.00
Initial Gross Cost:	3812.26
Initial Plan Pay:	1906.13
Gap Gross Cost:	3353.83
Gap Plan Pay:	2515.38
Catastrophic Gross Cost:	917.61
Catastrophic Plan Pay:	871.73

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Pharmacy Reimbursement

Reimbursement Type:
Reimbursement Number:
Reimbursement Amount:
Posting Date:
Reporting Number:

Reversal

Reimbursement Type:
Reimbursement Number:
Reimbursement Amount:
Posting Date:
Reporting Number:

[View Reimbursements](#)

Recipient

Name:
Alternate Name:
Address:
City:
State:
Zip:

[Go to top](#)

EXHIBIT 37

This transcript was exported on Apr 23, 2019 - view latest version [here](#).

[REDACTED]

I want more on meds. I don't want just anything.

Claudia:

Thank you for calling customer care. My name is Claudia. Can I please have the member ID?

[REDACTED]

Yes. It is [REDACTED]

Claudia:

Thank you ma'am. [crosstalk 00:00:24] And can I please ... go ahead, I'm sorry.

[REDACTED]

Your name was Claudia?

Claudia:

Yes. C-L-A-U-D-I-A.

[REDACTED]:

D-I-A. Okay.

Claudia:

Can I please have the full name, as it appears on the account, please?

[REDACTED]:

Is [REDACTED]

Claudia:

Thank you, what's the date of birth, and the zip code, please?

[REDACTED]

[REDACTED], and a zip code of [REDACTED]

Claudia:

Thank you, ma'am. Who do I have the pleasure of speaking with today?

[REDACTED]

This is [REDACTED] and [REDACTED] is here.

[REDACTED]

[inaudible 00:01:15].

Claudia:

I'm his wife.

[REDACTED]

Okay, thank you. May I speak to him just one second?

Claudia:

Yes.

[REDACTED]:
[REDACTED]

Thank you.

Claudia:

Hi, [REDACTED], may I speak to your wife regarding all information about your account?

[REDACTED]

Yes, ma'am, you can.

Claudia:

Okay, thank you sir, that's all I needed.

[REDACTED]

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[REDACTED]: Thank you. I'm going to go do that.

[REDACTED] Okay.

[REDACTED] [inaudible 00:01:34].

[REDACTED] All righty.

[REDACTED] [inaudible 00:01:39].

Claudia: Thank you, ma'am for that. So you said your name is [REDACTED] right?

[REDACTED] Yes.

Claudia: Okay, how can I help you today?

[REDACTED] Let's see. [REDACTED] has Hepatitis C, and this Eplusa prescription, we're trying to get a price on, so we know how much it's going to cost, if we can afford it. I'm either not getting any prices from people, because they say they have to have the prescription.

[REDACTED] The prescription was sent to Walmart, Walmart said that it was \$2,700 a month. We called a little bit ago and talked to Sierra at SilverScript, and she said it was \$1,255.99 co-pay, one time, for the complete 84-day supply. 84 pills. So we called back Walmart, and he double checked again, and he said he's still coming up with \$2,700 a month.

[REDACTED] [inaudible 00:02:58].

[REDACTED] For generic, and for us to call you back.

Claudia: Okay. Let me see what we can do about this. Is the original medication was the Eplusa Tablets 400-100 milligrams? Right? E-P-C-L-U-S-A? Eplusa.

[REDACTED] E-P-C-L-U-S-A.

Claudia: U-S-A. Perfect, okay.

[REDACTED] It's 84 pills, [crosstalk 00:03:28]. 84. Okay. Okay. We don't know what milligrams. What did you say the milligram was?

Claudia: Yes. It was 400-100 milligrams.

[REDACTED] 400-100 milligrams. Okay. This is for 84, okay?

[REDACTED]

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Claudia: Mm-hmm (affirmative), perfect. Let me run a test claim, to see what the co-pay would be. I'm going to run first a ... Let me see now. I'm going to do the 84, because you know that he would need it for 84 days, for sure.

[REDACTED] Okay, thank you.

Claudia: Mm-hmm (affirmative), you're welcome, ma'am. Okay, Walmart is not a preferred pharmacy. It was last year, but it's not this year.

[REDACTED] Oh, okay.

[REDACTED] [inaudible 00:04:41].

[REDACTED] What is a preferred pharmacy? Where would we get the best price?

Claudia: At the preferred pharmacy, you would get the better price.

[REDACTED] Okay, and what are the preferred pharmacies?

Claudia: You got two, ma'am. It's the Walgreens that is at [REDACTED] ...

[REDACTED] [REDACTED]

Claudia: [REDACTED]

[REDACTED] Okay, [REDACTED]

Claudia: Mm-hmm (affirmative). The other one is, are you ready?

[REDACTED] Let me finish this up.

Claudia: Sure, sorry.

[REDACTED] Walgreens at [REDACTED]

Claudia: [REDACTED]

[REDACTED] Road, and that's in [REDACTED]?

Claudia: [REDACTED] yes ma'am.

[REDACTED] Okay.

Claudia: The other one is [REDACTED]

[REDACTED]

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[REDACTED] Okay. [REDACTED]

Claudia: Pharmacy, mm-hmm (affirmative). It is #2 - [REDACTED]

[REDACTED] 344.

Claudia: [REDACTED], too.

[REDACTED] Okay.

Claudia: Let's check one of this ones.

[REDACTED] Okay.

Claudia: (long pause) One more second please, ma'am.

[REDACTED] Okay.

Claudia: Thank you. Okay, let me try to find something first. You were given two different co-pays for the local pharmacy, but they were for only 28-day supplies, the \$2,790. That was for a 28-day supply.

Claudia: The co-pay for an 84-day supply at the local pharmacy, not the Walmart one, the [REDACTED] would be \$5,642.54.

[REDACTED] Okay. And that's at [REDACTED]? For 84 days?

Claudia: Right. Let me check something here.

[REDACTED] Okay.

Claudia: Because I'm not sure if you can get the ...

[REDACTED] And we also are real close to [REDACTED] if that makes a difference, would be cheaper.

Claudia: Yes. [inaudible 00:07:55].

[REDACTED] [inaudible 00:07:54].

Claudia: Sofosbuvir, right? [inaudible 00:07:57].

[REDACTED] E-P-C-L-U-S-A.

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Claudia: That's the first one, yeah. That's [Eclusa 00:08:12], or Eclusa, right? You would like me to try the generic? Because I see there was another medication.

Okay.

Claudia: The generic that you were talking about, for \$2,790.46. Let me try that one, and also let me tell you something else. You're not able to get a 90-day supply, but a 28-day supply instead.

Claudia: We're going to start running a test for a 28-day supply, instead of 84.

Okay.

Claudia: Give me one second.

How do you spell the generic [inaudible 00:09:08]?

Claudia: The generic? It's two words. The first word is S, as in Sam - O - F as in Frank - O - S as in Sam - B as in Boy - U - V as in Victor - I - R as in Robert.

All right.

Claudia: Next word is V as in Victor - E - L as in Larry - P as in Peter - A - T as in Tom - A - S as in Sam - V as in Victor - I - R as in Robert. It's also tablets. And it's the same strength, 400-100 milligrams.

Claudia: So I just run a test claim for the first one, the Eclusa, and the 28-day supply at the local pharmacy would be \$3,130.61.

And which pharmacy is that at?

Claudia: This was at the, let me see, okay. Let me run the test again, because once I do it I don't see the name of the pharmacy. Give me one more second. (long pause)

[inaudible 00:11:22].

[inaudible 00:11:25].

Claudia: Okay, so the [redacted] And that's a co-pay. Now we go back to the next medication, Sofosbuvir. (long pause)

Claudia: Okay, for this other medication, the co-pay would be \$2,488.53, also.

So that's the 28-day supply of the generic?

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Claudia: 28-day supply.

[REDACTED]: And which pharmacy?

Claudia: That's [REDACTED] as well.

[REDACTED]: Okay. I thought the \$3,130 was [REDACTED], for the generic, for 28-day supply.

Claudia: Right. That's the Eplclusa tablets, which I can find. It's the brand name.

[REDACTED]: [inaudible 00:13:19].

Claudia: Mm-hmm (affirmative)? Go ahead.

[REDACTED]: This next Eplclusa 28-day supply is \$3,100 at [REDACTED], and the generic at [REDACTED] is \$2,488?

Claudia: Okay. Let me go back and see. I'm pulling up information to see which is the generic, and which is the brand.

[REDACTED]: Okay. That's for [REDACTED], 84-day?

[REDACTED]: [inaudible 00:13:52].

[REDACTED]: Yeah.

[REDACTED]: That's what you want. You don't want the [inaudible 00:13:57].

[REDACTED]: Yeah.

[REDACTED]: [inaudible 00:13:57].

Claudia: What I see here is, there are two ... the two of them are brands. Would you like me to bring the pharmacist technician? If you may stay on hold, I can ask the pharmacy technician to see what's the brand one, and what's the generic, because here in the system, they are shown as brand, both of them

[REDACTED]: All right.

Claudia: Please stay with me on the line.

[REDACTED]: Sure. I'll hold on, thank you.

Claudia: You're very welcome. Do you know if there's any alternatives for this medication?

[REDACTED]

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[REDACTED]

What was that for the medication?

Claudia:

I'm sorry. Do you know if there is any alternative? Did the doctors say something about it?

[REDACTED]

I ... yeah, the doctor didn't say, so we don't know.

Claudia:

Okay.

Speaker 4:

We'll have to ask the doctor.

Claudia:

Okay, let me see if I can get that information. In case the pharmacist technician needs to talk to you about something, I will bring you to the conversation. And, once you are done with the pharmacist technician, please remain with me on the line, okay?

Speaker 4:

Thank you.

Claudia:

Okay, thank you ma'am. (long pause)

Speaker 4:

Hello? Okay. Okay. Okay. Great, and can I get that price again from you, too? And that's for 28 days? Okay. After R was [TMM# 00:28:10]? Okay. And then P. And is that price ... which store is that from? Okay. And both of them are in

[REDACTED]

Speaker 4:

Do you have any located in [REDACTED] that might be just as cheap? Okay, things are cheaper out in [REDACTED]. Okay, for [REDACTED]. That's in [REDACTED]. Okay. All righty, it looks like we'll be changing our pharmacy, to the [REDACTED] in [REDACTED] [inaudible 00:30:10], okay.

Speaker 4:

And then the other one, the original first one that you gave me for 84 days, for Smith's, the co-pay was \$5,642.50? Could you double check that to make sure it's correct? Mm-hmm (affirmative). Okay, so that, that's not a valid ... okay. Only 28 days.

Speaker 4:

All righty. You have been so helpful. Thank you very much. I sure appreciate all your help on this. Nope, you did an excellent job. Great. Thank you, Claudia. You can have the rest of the day off. Good job. [inaudible 00:31:41]. Thank you very much. Bye bye.

[REDACTED]

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EXHIBIT 38

Peoplesafe

Page 1 of 1

CAREMARK **PeopleSafe®** Close

Eligibility Maintenance ☐ Participant Inquiry ☐ Resolution Manager ☐ Medicare Inquiry ☐ View Opportunities Tools: -- Select A Tool --

Client: [REDACTED] SILVERSCRIPT-INDIV-ENROLL System: RXCLAIM

External ID: [REDACTED] Name: [REDACTED] Gndr: M Relationship: MEMBER Born: [REDACTED] 1952 Effective: 01-01-2020 Expiration: 12-31-2039

Plan Benefit Override ☐ Account Balance ☐ Explanation of Benefits ☐ Transaction History ☐ Communication History ☐ Caremark.com ☐

Pharmacy Network ☐ Retail Transaction ☐ Plan Summary ☐ FSA/HSA/HRA History ☐ Coordination of Benefits ☐ Order Placement ☐ Adjustments ☐ Client Managed (G & A) ☐ View Triggers ☐

Prescription for: [REDACTED] MEMBER Delivery System: POINT OF SALE Dispense As Written: 0 - NO DAW
 Prescription Number: [REDACTED] [Go to Reimbursement...](#) Pharmacy NPI: [REDACTED] Drug Price Type: AVERAGE WHOLESALE PRICE
 Drug NDC: 61958220101 Pharmacy NCPDP: [REDACTED] Drug Price Source: MEDISPAN
 Drug Name: EPLUSA Pharmacy Name: [REDACTED] Client Claim Price Type: Pharmacy Claim Price Type:

Participant Pay Participant Copay: 8.35 Initial Copay: 735.20 Gap Copay: 3821.19 Catastrophic Copay: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 8.35	Client Pay Usual and Customary: 37380.00 Cost Submitted: 37380.00 Cost Allowed: 25253.93 Other Payer Recognized: 0.00 Dispensing Fee: 0.50 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 25246.08	Pharmacy Pay: Usual and Customary: 25253.93 Cost Allowed: 25253.93 Other Payer Recognized: 0.00 Dispensing Fee: 0.50 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 25246.08
--	--	--

Health Reimbursement Account:
 Benefits: 0.00
 Member Access Fee: 0.00
 Amount Used: 0.00
 HRA Remaining Balance: 0.00

Med D Financials:
 LICs Paid by Plan: 5508.30
 SPAP/Integrator Paid Amt: 0.00
 Reported Gap Discount: 0.00
 Deductible Gross Cost: 0.00
 Deductible Plan Pay: 0.00
 Initial Gross Cost: 2227.89
 Initial Plan Pay: 1492.69
 Gap Gross Cost: 3821.19
 Gap Plan Pay: 0.00
 Catastrophic Gross Cost: 19205.33
 Catastrophic Plan Pay: 18245.09

Miscellaneous
 Applied To Out of Pocket: 0.00
 Applied To TROOP: 0.00
 Applied To OOPM/MOOP: 0.00
 Paid by Other Insurance: 0.00
 Alternate Amount Paid: 0.00
 Previous Amount Paid: 0.00
 In Network Accumulation: 0.00
 Out of Network Accumulation: 0.00

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Pharmacy Reimbursement

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

Reversal

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

[View Reimbursements](#)

Recipient

Name:
 Alternate Name:
 Address:
 City:
 State:
 Zip:

[Go to top](#)

EXHIBIT 39

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Important: This notice explains your right to appeal our decision. Read this notice carefully. If you need help, you can call one of the numbers listed on the last page under "Get help & more information."



P.O. Box 30003, Pittsburgh, PA 15222-0330
1-866-235-5660

NOTICE OF DENIAL OF MEDICARE PART D PRESCRIPTION DRUG COVERAGE

Date: 01/11/2019	
Enrollee's Name: [REDACTED]	Member Number: [REDACTED]
<p>Your request was denied We have denied coverage or payment under your Medicare Part D benefit for the following prescription drug(s) that you or your prescriber requested: LEDIPASVIR/SOFOSBUVIR Tablet</p> <p>Why did we deny your request? We denied this request under Medicare Part D because: Your Medicare Part D drug plan was asked to cover a drug that is not on the formulary (this is called a formulary exception). The generic drug you requested ledipasvir/sofosbuvir is not on your plan's formulary (list of covered drugs). Your plan covers the Brand version of this drug, Harvoni.</p> <p>Both the brand Harvoni and generic version of this drug, ledipasvir/sofosbuvir, would be expected to have the same effectiveness in treating your condition. The brand drug on the formulary and its generic contain the same active medications. They both contain the same inactive ingredients such as dyes, and would be expected to have the same risk of causing adverse effects (side effects). Talk to your prescriber to see if any of the formulary alternative(s) would be right for you.</p> <p>Additional formulary alternatives that may be an appropriate choice for you are:</p> <p>Epclusa (Prior authorization required) Mavyret Tablet (Prior authorization required) Vosevi (Prior authorization required) Zepatier (Prior authorization required)</p> <p>You should share a copy of this decision with your prescriber so you and your prescriber can discuss next steps. If your prescriber requested coverage on your behalf, we have shared this decision with your prescriber.</p>	

What If I Don't Agree With This Decision?

You have the right to appeal. If you want to appeal, you must request your appeal within 60 calendar days after the date of this notice. We can give you more time if you have a good reason for missing the deadline. You have the right to ask us for a **formulary exception** if you believe you need a

[REDACTED]

[REDACTED]

(Expires 02/29/2020)

drug that is not on our list of covered drugs (formulary). You have the right to ask us for a **coverage rule exception** if you believe a rule such as prior authorization or a quantity limit should not apply to you. You can either provide information that shows that you meet the coverage rule that applies to the drug you are requesting or you can ask for a coverage rule exception. You can ask for a **tiering exception** if you believe you should get a drug at a lower cost-sharing amount. Your prescriber must provide a statement to support your exception request.

Who May Request an Appeal?

You, your prescriber, or your representative may request an expedited (fast) or standard appeal. You can name a relative, friend, advocate, attorney, doctor, or someone else to be your representative. Others may already be authorized under State law to be your representative.

You can call us at: 1-866-235-5660 to learn how to appoint a representative. If you have a hearing or speech impairment, please call us at TTY: 711.

IMPORTANT INFORMATION ABOUT YOUR APPEAL RIGHTS

There Are Two Kinds of Appeals You Can Request

Expedited (72 hours): You, your prescriber, or your representative can request an expedited (fast) appeal if you or your prescriber believe that your health could be seriously harmed by waiting up to 7 days for a decision. You cannot request an expedited appeal if you are asking us to pay you back for a prescription drug you already received. If your request to expedite is granted, we must give you a decision no later than 72 hours after we get your appeal.

- * **If your prescriber** asks for an expedited appeal for you, or supports you in asking for one, and indicates that waiting for 7 days could seriously harm your health, **we will automatically expedite your appeal.**
- * If you ask for an expedited appeal without support from your prescriber, we will decide if your health requires an expedited appeal. We will notify you if we do not give you an expedited appeal and we will decide your appeal within 7 days.

Standard (7 days): You, your prescriber, or your representative can request a standard appeal. We must give you a decision no later than 7 days after we get your appeal.

What Do I Include with My Appeal Request?

You should include your name, address, Member number, the reasons for appealing, and any evidence you wish to attach. Remember, your doctor must provide us with a supporting statement if you're requesting an exception to a coverage rule. You should include information about why the coverage rule should not apply to you because of your specific medical condition. If your appeal relates to a decision by us to deny a drug that is not on our formulary, your prescriber must indicate that all the drugs on any tier of our formulary would not be as effective to treat your condition as the requested off-formulary drug or would harm your health.

How Do I Request an Appeal?

For an Expedited Appeal: You, your prescriber, or your representative should contact us by telephone or fax at the numbers below:

Phone: 1-866-235-5660
TTY: 711
Fax: 1-855-633-7673

For a Standard Appeal: You, your prescriber, or your representative should mail or deliver your written appeal request to the address below:

CVS Caremark Part D Appeals and Exceptions
P.O. Box 52000, MC109
Phoenix, AZ 85072-2000
Phone: 1-866-235-5660
TTY: 711

What Happens Next?

If you appeal, we will review your case and give you a decision. If any of the prescription drugs you requested are still denied, you can request an independent review of your case by a reviewer outside of your Medicare Drug Plan. If you disagree with that decision, you will have the right to further appeal. You will be notified of your appeal rights if this happens.

Get help & more information

- SilverScript Choice (PDP) Toll Free: 1-866-235-5660
TTY users call: 711
24 hours a day, 7 days a week
www.silverscript.com
- 1-800-MEDICARE (1-800-633-4227), 24 hours, 7 days a week. TTY users call: 1-877-486-2048
- Medicare Rights Center: 1-888-HMO-9050
- Elder Care Locator: 1-800-677-1116
- State Health Insurance Program National Technical Assistance Center: 877-839-2675

PRA Disclosure Statement According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection is 0938-0976. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, and gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

CMS does not discriminate in its programs and activities: To request this form in an accessible format (e.g., Braille, Large Print, Audio CD) contact your Medicare Drug Plan. If you need assistance contacting your plan, call: 1-800-MEDICARE.



Request for Redetermination of Medicare Prescription Drug Denial

Because we, SilverScript Choice (PDP), denied your request for coverage of (or payment for) a prescription drug, you have the right to ask us for a redetermination (appeal) of our decision. You have 60 days from the date of our Notice of Denial of Medicare Prescription Drug Coverage to ask us for a redetermination. This form may be sent to us by mail or fax:

Address:	Fax Number:
CVS Caremark Part D Appeals and Exceptions	1-855-633-7673
P.O. Box 52000, MC109	
Phoenix, AZ 85072-2000	

You may also ask us for an appeal through our website at www.silverscript.com. Expedited appeal requests can be made by phone at 1-866-235-5660, TTY: 711, 24 hours a day, 7 days a week.

Who May Make a Request: Your prescriber may ask us for an appeal on your behalf. If you want another individual (such as a family member or friend) to request an appeal for you, that individual must be your representative. Contact us to learn how to name a representative.

Enrollee's Information		
Enrollee's Name _____	Date of Birth _____	
Enrollee's Address _____		
City _____	State _____	Zip Code _____
Phone _____	Enrollee's Plan ID Number _____	
Complete the following section ONLY if the person making this request is not the enrollee:		
Requestor's Name _____		
Requestor's Relationship to Enrollee _____		
Address _____		
City _____	State _____	Zip Code _____
Phone _____		
<u>Representation documentation for appeal requests made by someone other than enrollee or the enrollee's prescriber:</u>		
<p>Attach documentation showing the authority to represent the enrollee (a completed Authorization of Representation Form CMS-1696 or a written equivalent) if it was not submitted at the coverage determination level. For more information on appointing a representative, contact your plan or 1-800-Medicare, 24 hours a day, 7 days a week. TTY users call: 1-877-486-2048</p>		

Prescription drug you are requesting:

Name of drug: _____ Strength/quantity/dose: _____

Have you purchased the drug pending appeal? ☐ Yes ☐ No

If "Yes": Date purchased: _____ Amount paid: \$ _____ (attach copy of receipt)

Name and telephone number of pharmacy: _____

Prescriber's Information

Name _____

Address _____

City _____ State _____ Zip Code _____

Office Phone _____ Fax _____

Office Contact Person _____

Important Note: Expedited Decisions

If you or your prescriber believe that waiting 7 days for a standard decision could seriously harm your life, health, or ability to regain maximum function, you can ask for an expedited (fast) decision. If your prescriber indicates that waiting 7 days could seriously harm your health, we will automatically give you a decision within 72 hours. If you do not obtain your prescriber's support for an expedited appeal, we will decide if your case requires a fast decision. You cannot request an expedited appeal if you are asking us to pay you back for a drug you already received.

☐ **CHECK THIS BOX IF YOU BELIEVE YOU NEED A DECISION WITHIN 72 HOURS****(If you have a supporting statement from your prescriber, attach it to this request.)**

Please explain your reasons for appealing. Attach additional pages, if necessary. Attach any additional information you believe may help your case, such as a statement from your prescriber and relevant medical records. You may want to refer to the explanation we provided in the Notice of Denial of Medicare Prescription Drug Coverage.

Signature of person requesting the appeal (the enrollee, or the enrollee's prescriber or representative):**Date:** _____

SilverScript is a Prescription Drug Plan with a Medicare contract offered by SilverScript Insurance Company. Enrollment in SilverScript depends on contract renewal.

ATENCIÓN: Si usted habla español, tenemos servicios de asistencia lingüística disponibles para usted

sin costo alguno. Llame al 1-866-235-5660 (TTY: 711).

The formulary may change at any time. You will receive notice when necessary.

EXHIBIT 40

Peoplesafe

Page 1 of 1

CAREMARK **PeopleSafe®** Close

Eligibility Maintenance ☐ Participant Inquiry ☐ Resolution Manager ☐ Medicare Inquiry ☐ View Opportunities Tools: -- Select A Tool --

Client: [REDACTED] - SILVERSCRIPT-INDIV-ENROLL System: RXCLAIM

External ID: [REDACTED] Name: [REDACTED] Gndr: M Relationship: MEMBER Born: [REDACTED] 1952 Effective: 01-01-2020 Expiration: 12-31-2039

Plan: [REDACTED] Plan Summary: [REDACTED] FSA/HSA/HRA History: [REDACTED] Coordination of Benefits: [REDACTED] Order Placement: [REDACTED] Adjustments: [REDACTED] Client Managed (G & A): [REDACTED] View Triggers

Pharmacy Network: [REDACTED] Retail Transaction: [REDACTED] Prescription for: [REDACTED] MEMBER Delivery System: POINT OF SALE Dispense As Written: 0 - NO DAW

Prescription Number: [REDACTED] [Go to Reimbursement...](#) Pharmacy NPI: [REDACTED] Drug Price Type: AVERAGE WHOLESALE PRICE

Drug NDC: 72626270101 Pharmacy NCPDP: [REDACTED] Drug Price Source: MEDISPAN

Drug Name: [SCF056UWR-VELPATASVIR](#) Pharmacy Name: [REDACTED] Client Claim Price Type: [REDACTED]

Pharmacy Claim Price Type: [REDACTED]

Participant Pay Participant Copy: 0.00 Initial Copy: 0.00 Gap Copy: 0.00 Catastrophic Copy: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 0.00	Client Pay Usual and Customary: Cost Submitted: 9600.00 Cost Allowed: 8083.20 Other Payer Recognized: 0.00 Dispensing Fee: 0.50 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 8083.70	Pharmacy Pay: Usual and Customary: Cost Allowed: 8083.20 Other Payer Recognized: 0.00 Dispensing Fee: 0.50 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 8083.70
---	--	---

Health Reimbursement Account:
 Benefits: 0.00
 Member Access Fee: 0.00
 Amount Used: 0.00
 HRA Remaining Balance: 0.00

Med D Financials:
 LICIS Paid by Plan: 404.18
 SPAP/Integrator Paid Amt: 0.00
 Reported Gap Discount: 0.00
 Deductible Gross Cost: 0.00
 Deductible Plan Pay: 0.00
 Initial Gross Cost: 0.00
 Initial Plan Pay: 0.00
 Gap Gross Cost: 0.00
 Gap Plan Pay: 0.00
 Catastrophic Gross Cost: 8083.70
 Catastrophic Plan Pay: 7679.52

Miscellaneous
 Applied To Out of Pocket: 0.00
 Applied To TROOP: 0.00
 Applied To OOPM/MOOP: 0.00
 Paid by Other Insurance: 0.00
 Alternate Amount Paid: 0.00
 Previous Amount Paid: 0.00
 In Network Accumulation: 0.00
 Out of Network Accumulation: 0.00

[View Settlement Codes](#) [View Comments](#) [Back](#)

Pharmacy Reimbursement

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

Reversal

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

[View Reimbursements](#)

Recipient

Name:
 Alternate Name:
 Address:
 City:
 State:
 Zip:

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EXHIBIT 41

Peoplesafe

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CAREMARK **PeopleSafe®** Close

Eligibility Maintenance ☐ Participant Inquiry ☐ Resolution Manager ☐ Medicare D Inquiry ☐ View Opportunities Tools: -- Select A Tool --

Client: **SILVERSCRIPT-INDIV-ENROLL** System: **RXCLAIM**

External ID: **[REDACTED]** Name: **[REDACTED]** Gndr: **M** Relationship: **MEMBER** Born: **[REDACTED] 1952** Effective: **01-01-2020** Expiration: **12-31-2039**

Main Screen Financial Details View Activity Prescription History Test Claims Plan Benefit Override Account Balance Explanation of Benefits Transaction History Communication History Caremark.com

Pharmacy Network Retail Transaction Plan Summary FSA/HSA/HRA History Coordination of Benefits Order Placement Adjustments Client Managed (G & A) View Triggers

Prescription for: **[REDACTED] MEMBER** Delivery System: **POINT OF SALE** Dispense As Written: **0 - NO DAW**

Prescription Number: **[REDACTED]** [Go to Reimbursement...](#) Pharmacy NPI: **[REDACTED]** Drug Price Type: **AVERAGE WHOLESALE PRICE**

Drug NDC: **61958220101** Pharmacy NCPDP: **[REDACTED]** Drug Price Source: **MEDISPAN**

Drug Name: **EPLUSA** Pharmacy Name: **CAREMARK SPECIALTY PHARMACY [REDACTED]** Client Claim Price Type: **[REDACTED]** Pharmacy Claim Price Type: **[REDACTED]**

Participant Pay Participant Copy: 8.50 Initial Copy: 1256.51 Gap Copy: 3831.11 Catastrophic Copy: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 8.50	Client Pay Usual and Customary: Cost Submitted: 52332.00 Cost Allowed: 25179.17 Other Payer Recognized: 0.00 Dispensing Fee: 0.50 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 25171.17	Pharmacy Pay: Usual and Customary: Cost Allowed: 25179.17 Other Payer Recognized: 0.00 Dispensing Fee: 0.50 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 25171.17
---	---	---

Health Reimbursement Account:

Benefits: 0.00	Miscellaneous
Member Access Fee: 0.00	Applied To Out of Pocket: 0.00
Amount Used: 0.00	Applied To TROOP: 0.00
HRA Remaining Balance: 0.00	Applied To OOPM/MOOP: 0.00
	Paid by Other Insurance: 0.00
	Alternate Amount Paid: 0.00
	Previous Amount Paid: 0.00
	In Network Accumulation: 0.00
	Out of Network Accumulation: 0.00

Med D Financials:

LICS Paid by Plan: 5956.16
SPAP/Integrator Paid Amt: 0.00
Reported Gap Discount: 0.00
Deductible Gross Cost: 0.00
Deductible Plan Pay: 0.00
Initial Gross Cost: 3807.62
Initial Plan Pay: 2551.11
Gap Gross Cost: 3831.11
Gap Plan Pay: 0.00
Catastrophic Gross Cost: 17540.94
Catastrophic Plan Pay: 16663.90

View Settlement Codes View Comments Back

Pharmacy Reimbursement

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

Reversal

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

[View Reimbursements](#)

Recipient

Name:
 Alternate Name:
 Address:
 City:
 State:
 Zip:

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EXHIBIT 42

Peoplesafe

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CAREMARK **PeopleSafe®** Close

Eligibility Maintenance **N** Participant Inquiry **N** Resolution Manager **N** Medicare D Inquiry **N** View Opportunities Tools: -- Select A Tool --

Client: **SILVERSCRIPT-INDIV-ENROLL** System: **RXCLAIM**

External ID: **[REDACTED]** Name: **[REDACTED]** Gndr: **M** Relationship: **MEMBER** DOB: **[REDACTED] 1952** Effective: **01-01-2020** Expiration: **12-31-2039**

Main Screen Financial Details View Activity Prescription History Test Claims Plan Benefit Override Account Balance Explanation of Benefits Transaction History Communication History Caremark.com

Pharmacy Network Retail Transaction Plan Summary FSA/HSA/HRA History Coordination of Benefits Order Placement Adjustments Client Managed (G & A) View Triggers

Prescription for: **[REDACTED] MEMBER** Delivery System: **POINT OF SALE** Dispense As Written: **0 - NO DAW**

Prescription Number: **[REDACTED]** [Go to Reimbursement...](#) Pharmacy NPI: **[REDACTED]** Drug Price Type: **AVERAGE WHOLESALE PRICE**

Drug NDC: **61958220101** Pharmacy NCPDP: **[REDACTED]** Drug Price Source: **MEDISPAN**

Drug Name: **EPLUSA** Pharmacy Name: **CAREMARK SPECIALTY PHARMACY [REDACTED]** Client Claim Price Type: **[REDACTED]** Pharmacy Claim Price Type: **[REDACTED]**

Participant Pay Participant Copy: 0.00 Initial Copy: 0.00 Gap Copy: 0.00 Catastrophic Copy: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 0.00	Client Pay Usual and Customary: Cost Submitted: 52332.00 Cost Allowed: 25179.17 Other Payer Recognized: 0.00 Dispensing Fee: 0.50 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 25179.67	Pharmacy Pay: Usual and Customary: Cost Allowed: 25179.17 Other Payer Recognized: 0.00 Dispensing Fee: 0.50 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 25179.67
---	---	---

Health Reimbursement Account:
 Benefits: 0.00
 Member Access Fee: 0.00
 Amount Used: 0.00
 HRA Remaining Balance: 0.00

Med D Financials:
 LICs Paid by Plan: 1258.99
 SPAP/Integrator Paid Amt: 0.00
 Reported Gap Discount: 0.00
 Deductible Gross Cost: 0.00
 Deductible Plan Pay: 0.00
 Initial Gross Cost: 0.00
 Initial Plan Pay: 0.00
 Gap Gross Cost: 0.00
 Gap Plan Pay: 0.00
 Catastrophic Gross Cost: 25179.67
 Catastrophic Plan Pay: 23920.69

Miscellaneous
 Applied To Out of Pocket: 0.00
 Applied To TROOP: 0.00
 Applied To OOPM/MOOP: 0.00
 Paid by Other Insurance: 0.00
 Alternate Amount Paid: 0.00
 Previous Amount Paid: 0.00
 In Network Accumulation: 0.00
 Out of Network Accumulation: 0.00

View Settlement Codes View Comments Back

Pharmacy Reimbursement

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

Reversal

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

[View Reimbursements](#)

Recipient

Name:
 Alternate Name:
 Address:
 City:
 State:
 Zip:

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EXHIBIT 43

Peoplesafe

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CAREMARK **PeopleSafe®** Close

Eligibility Maintenance Participant Inquiry Resolution Manager Medicare Inquiry View Opportunities Tools: -- Select A Tool --

Client: **SILVERSCRIPT-INDIV-ENROLL** System: **RXCLAIM**

External ID: **[REDACTED]** Name: **[REDACTED]** Gndr: **M** Relationship: **MEMBER** Born: **[REDACTED] 1952** Effective: **01-01-2020** Expiration: **12-31-2039**

[Main Screen](#) [Financial Details](#) [View Activity](#) [Prescription History](#) [Test Claims](#) [Plan Benefit Override](#) [Account Balance](#) [Explanation of Benefits](#) [Transaction History](#) [Communication History](#) [Carmark.com](#)

[Pharmacy Network](#) [Retail Transaction](#) [Plan Summary](#) [FSA/HSA/HRA History](#) [Coordination of Benefits](#) [Order Placement](#) [Adjustments](#) [Client Managed G & A](#) [View Triggers](#)

Prescription for: **[REDACTED] MEMBER** Delivery System: **POINT OF SALE**
 Prescription Number: **[REDACTED]** [Go to Reimbursement...](#) Pharmacy NPI: **[REDACTED]**
 Drug NDC: **61958220101** Pharmacy NCPDP: **[REDACTED]**
 Drug Name: **EPCLUSA** Pharmacy Name: **[REDACTED]**

Dispense As Written: **0 - NO DAW**
 Drug Price Type: **AVERAGE WHOLESALE PRICE**
 Drug Price Source: **MEDISPAN**
 Client Claim Price Type: **[REDACTED]**
 Pharmacy Claim Price Type: **[REDACTED]**

Participant Pay Participant Copy: 0.00 Initial Copy: 0.00 Gap Copy: 0.00 Catastrophic Copy: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 0.00	Client Pay Usual and Customary: Cost Submitted: 29904.00 Cost Allowed: 25179.17 Other Payer Recognized: 0.00 Dispensing Fee: 0.50 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 25179.67	Pharmacy Pay: Usual and Customary: Cost Allowed: 25179.17 Other Payer Recognized: 0.00 Dispensing Fee: 0.50 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 25179.67
---	---	---

Health Reimbursement Account:
 Benefits: 0.00
 Member Access Fee: 0.00
 Amount Used: 0.00
 HRA Remaining Balance: 0.00

Med D Financials:
 LICR Paid by Plan: 1258.99
 SPAP/Integrator Paid Amt: 0.00
 Reported Gap Discount: 0.00
 Deductible Gross Cost: 0.00
 Deductible Plan Pay: 0.00
 Initial Gross Cost: 0.00
 Initial Plan Pay: 0.00
 Gap Gross Cost: 0.00
 Gap Plan Pay: 0.00
 Catastrophic Gross Cost: 25179.67
 Catastrophic Plan Pay: 23920.69

Miscellaneous
 Applied To Out of Pocket: 0.00
 Applied To TROOP: 0.00
 Applied To OOP/MOOP: 0.00
 Paid by Other Insurance: 0.00
 Alternate Amount Paid: 0.00
 Previous Amount Paid: 0.00
 In Network Accumulation: 0.00
 Out of Network Accumulation: 0.00

[View Settlement Codes](#) [View Comments](#) [Back](#)

Pharmacy Reimbursement

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

Reversal

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

[View Reimbursements](#)

Recipient

Name:
 Alternate Name:
 Address:
 City:
 State:
 Zip:

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EXHIBIT 44

Mail		All									
Delivery System Method	Order	Participant	Rx Number	Posted / Future Fill	Filled	Dispensed Drug	Pharmacy	Fills Left / Next Refill	Status Date / Status	Ship Method / Tracking	
POINT OF SALE				02-12-2019	02-12-2019	90MG-400MG HARVONI-TABLET-90MG-400MG			Reversal		^
POINT OF SALE				02-12-2019	02-12-2019	HARVONI-TABLET-90MG-400MG			Rejected		
POINT OF SALE				02-06-2019	02-06-2019	HARVONI-TABLET-90MG-400MG			Rejected		
POINT OF SALE				02-06-2019	02-06-2019	LEDIPASVIR-SOFOSBUVIR-TABLET-90MG-400MG			Rejected		v
Maintain Patient Profile		Order Card, Kit		Order Fulfillment		View Comments ✓		Maintain Payment Options		Eligibility	Clear

EXHIBIT 45

(Rev 01/2019)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Important: This notice explains your right to appeal our decision. Read this notice carefully. If you need help, you can call one of the numbers listed on the last page under "Get help & more information."

SilverScript®

P.O. Box 30003, Pittsburgh, PA 15222-0330
1-866-235-5660

NOTICE OF DENIAL OF MEDICARE PART D PRESCRIPTION DRUG COVERAGE

Date: 02/12/2019

Enrollee's Name: [REDACTED]

Member Number: [REDACTED]

Your request was denied

We have denied coverage or payment under your Medicare Part D benefit for the following prescription drug(s) that you or your prescriber requested: LEDIPASVIR/SOFOSBUVIR Tablet

Why did we deny your request?

We denied this request under Medicare Part D because: Your Medicare Part D drug plan was asked to cover a drug that is not on the formulary (this is called a formulary exception). The generic drug you requested ledipasvir/sofosbuvir is not on your plan's formulary (list of covered drugs). Your plan covers the Brand version of this drug, Harvoni.

Both the brand Harvoni and generic version of this drug, ledipasvir/sofosbuvir, would be expected to have the same effectiveness in treating your condition. The brand drug on the formulary and its generic contain the same active medications. They both contain the same inactive ingredients such as dyes, and would be expected to have the same risk of causing adverse effects (side effects). Talk to your prescriber to see if any of the formulary alternative(s) would be right for you.

Additional formulary alternatives that may be an appropriate choice for you are:

Epclusa (Prior authorization required)
Mavyret Tablet (Prior authorization required)
Vosevi (Prior authorization required)

(Rev 01/2019)

Zepatier (Prior authorization required)

You should share a copy of this decision with your prescriber so you and your prescriber can discuss next steps. If your prescriber requested coverage on your behalf, we have shared this decision with your prescriber.

What If I Don't Agree With This Decision?

You have the right to appeal. If you want to appeal, you must request your appeal within 60 calendar days after the date of this notice. We can give you more time if you have a good reason for missing the deadline. You have the right to ask us for a **formulary exception** if you believe you need a drug that is not on our list of covered drugs (formulary). You have the right to ask us for a **coverage rule exception** if you believe a rule such as prior authorization or a quantity limit should not apply to you. You can either provide information that shows that you meet the coverage rule that applies to the drug you are requesting or you can ask for a coverage rule exception. You can ask for a **tiering exception** if you believe you should get a drug at a lower cost-sharing amount. Your prescriber must provide a statement to support your exception request.

Who May Request an Appeal?

You, your prescriber, or your representative may request an expedited (fast) or standard appeal. You can name a relative, friend, advocate, attorney, doctor, or someone else to be your representative. Others may already be authorized under State law to be your representative.

You can call us at: 1-866-235-5660 to learn how to appoint a representative. If you have a hearing or speech impairment, please call us at TTY: 711.

(Rev 01/2019)

IMPORTANT INFORMATION ABOUT YOUR APPEAL RIGHTS

There Are Two Kinds of Appeals You Can Request

Expedited (72 hours): You, your prescriber, or your representative can request an expedited (fast) appeal if you or your prescriber believe that your health could be seriously harmed by waiting up to 7 days for a decision. You cannot request an expedited appeal if you are asking us to pay you back for a prescription drug you already received. If your request to expedite is granted, we must give you a decision no later than 72 hours after we get your appeal.

- * **If your prescriber** asks for an expedited appeal for you, or supports you in asking for one, and indicates that waiting for 7 days could seriously harm your health, **we will automatically expedite your appeal.**
- * If you ask for an expedited appeal without support from your prescriber, we will decide if your health requires an expedited appeal. We will notify you if we do not give you an expedited appeal and we will decide your appeal within 7 days.

Standard (7 days): You, your prescriber, or your representative can request a standard appeal. We must give you a decision no later than 7 days after we get your appeal. If your appeal is for payment of a drug you've already received, we'll give you a written decision within 14 days.

What Do I Include with My Appeal Request?

You should include your name, address, Member number, the reasons for appealing, and any evidence you wish to attach. Remember, your doctor must provide us with a supporting statement if you're requesting an exception to a coverage rule. You should include information about why the coverage rule should not apply to you because of your specific medical condition. If your appeal relates to a decision by us to deny a drug that is not on our formulary, your prescriber must indicate that all the drugs on any tier of our formulary would not be as effective to treat your condition as the requested off-formulary drug or would harm your health.

How Do I Request an Appeal?

For an Expedited Appeal: You, your prescriber, or your representative should contact us by telephone or fax at the numbers below:

Phone: 1-866-235-5660
TTY: 711
Fax: 1-855-633-7673

For a Standard Appeal: You, your prescriber, or your representative should mail or deliver your written appeal request to the address below:

CVS Caremark Part D Appeals and Exceptions
P.O. Box 52000, MC109
Phoenix, AZ 85072-2000
Phone: 1-866-235-5660
TTY: 711

(Rev 01/2019)

What Happens Next?

If you appeal, we will review your case and give you a decision. If any of the prescription drugs you requested are still denied, you can request an independent review of your case by a reviewer outside of your Medicare Drug Plan. If you disagree with that decision, you will have the right to further appeal. You will be notified of your appeal rights if this happens.

Get help & more information

- SilverScript Choice (PDP) Toll Free: 1-866-235-5660
TTY users call: 711
24 hours a day, 7 days a week
www.silverscript.com
- 1-800-MEDICARE (1-800-633-4227), 24 hours, 7 days a week. TTY users call: 1-877-486-2048
- Medicare Rights Center: 1-888-HMO-9050
- Elder Care Locator: 1-800-677-1116
- State Health Insurance Program National Technical Assistance Center: 877-839-2675

PRA Disclosure Statement According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection is 0938-0976. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, and gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

CMS does not discriminate in its programs and activities: To request this form in an accessible format (e.g., Braille, Large Print, Audio CD) contact your Medicare Drug Plan. If you need assistance contacting your plan, call: 1-800-MEDICARE.



Request for Redetermination of Medicare Prescription Drug Denial

Because we, SilverScript Choice (PDP), denied your request for coverage of (or payment for) a prescription drug, you have the right to ask us for a redetermination (appeal) of our decision. You have 60 days from the date of our Notice of Denial of Medicare Prescription Drug Coverage to ask us for a redetermination. This form may be sent to us by mail or fax:

Address:
CVS Caremark Part D Appeals and Exceptions
P.O. Box 52000, MC109
Phoenix, AZ 85072-2000

Fax Number:
1-855-633-7673

You may also ask us for an appeal through our website at www.silverscript.com. Expedited appeal requests can be made by phone at 1-866-235-5660, TTY: 711, 24 hours a day, 7 days a week.

Who May Make a Request: Your prescriber may ask us for an appeal on your behalf. If you want another individual (such as a family member or friend) to request an appeal for you, that individual must be your representative. Contact us to learn how to name a representative.

Enrollee's Information

Enrollee's Name _____ Date of Birth _____

Enrollee's Address _____

City _____ State _____ Zip Code _____

Phone _____ Enrollee's Plan ID Number _____

Complete the following section ONLY if the person making this request is not the enrollee:

Requestor's Name _____

Requestor's Relationship to Enrollee _____



Address _____		
City _____	State _____	Zip Code _____
Phone _____		
<u>Representation documentation for appeal requests made by someone other than enrollee or the enrollee's prescriber:</u>		
Attach documentation showing the authority to represent the enrollee (a completed Authorization of Representation Form CMS-1696 or a written equivalent) if it was not submitted at the coverage determination level. For more information on appointing a representative, contact your plan or 1-800-Medicare, 24 hours a day, 7 days a week. TTY users call: 1-877-486-2048		
Prescription drug you are requesting:		
Name of drug: _____ Strength/quantity/dose: _____		
Have you purchased the drug pending appeal? <input type="checkbox"/> Yes <input type="checkbox"/> No		
If "Yes": Date purchased: _____ Amount paid: \$ _____ (attach copy of receipt)		
Name and telephone number of pharmacy: _____		

Prescriber's Information		
Name _____		
Address _____		
City _____	State _____	Zip Code _____
Office Phone _____	Fax _____	
Office Contact Person _____		

Important Note: Expedited Decisions

If you or your prescriber believe that waiting 7 days for a standard decision could seriously harm your life, health, or ability to regain maximum function, you can ask for an expedited (fast) decision. If your prescriber indicates that waiting 7 days could seriously harm your health, we will automatically give you a decision within 72 hours. If you do not obtain your prescriber's support for an expedited appeal, we will decide if your case requires a fast decision. You cannot request an expedited appeal if you are asking us to pay you back for a drug you already received.

☐ **CHECK THIS BOX IF YOU BELIEVE YOU NEED A DECISION WITHIN 72 HOURS**
(If you have a supporting statement from your prescriber, attach it to this request.)

Please explain your reasons for appealing. Attach additional pages, if necessary. Attach any additional information you believe may help your case, such as a statement from your prescriber and relevant medical records. You may want to refer to the explanation we provided in the Notice of Denial of Medicare Prescription Drug Coverage.

Signature of person requesting the appeal (the enrollee, or the enrollee's prescriber or representative):

Date: _____

SilverScript is a Prescription Drug Plan with a Medicare contract offered by SilverScript Insurance Company. Enrollment in SilverScript depends on contract renewal.

ATENCIÓN: Si usted habla español, tenemos servicios de asistencia lingüística disponibles para usted sin costo alguno. Llame al 1-866-235-5660 (TTY: 711).

The formulary may change at any time. You will receive notice when necessary.

EXHIBIT 46

Peoplesafe

Page 1 of 1

CAREMARK **PeopleSafe®** Close

Eligibility Maintenance ☐ Participant Inquiry ☐ Resolution Manager ☐ Medicare D Inquiry ☐ View Opportunities Tools: -- Select A Tool --

Client: SILVERSCRIPT-INDIV-ENROLL **System:** RXCLAIM

External ID: **Name:** **Gndr:** F **Relationship:** MEMBER **Born:** 1942 **Effective:** 01-01-2020 **Expiration:** 12-31-2039

[Main Screen](#) [Financial Details](#) [View Activity](#) [Prescription History](#) [Test Claims](#) [Plan Benefit Overview](#) [Account Balance](#) [Explanation of Benefits](#) [Transaction History](#) [Communication History](#) [Caremark.com](#)

[Pharmacy Network](#) [Retail Transaction](#) [Plan Summary](#) [FSA/HSA/HRA History](#) [Coordination of Benefits](#) [Order Placement](#) [Adjustments](#) [Client Managed \(G & A\)](#) [View Triggers](#)

Prescription for: **MEMBER** **Delivery System:** POINT OF SALE **Dispense As Written:** 1 - PHYSICIAN DAW
Prescription Number: [Go to Reimbursement...](#) **Pharmacy NPI:** **Drug Price Type:** AVERAGE WHOLESALE PRICE
Drug NDC: 61956220101 **Pharmacy NCPDP:** **Drug Price Source:** MEDISPAN
Drug Name: [EPLUSA](#) **Pharmacy Name:** **Client Claim Price Type:** **Pharmacy Claim Price Type:**

Participant Pay Participant Copay: 3.80 Initial Copay: 1248.51 Gap Copay: 3814.88 Catastrophic Copay: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 3.80	Client Pay Usual and Customary: 35884.80 Cost Submitted: 25119.36 Cost Allowed: 25119.36 Other Payer Recognized: 0.00 Dispensing Fee: 0.40 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 25115.96	Pharmacy Pay: Usual and Customary: 25119.36 Cost Allowed: 25119.36 Other Payer Recognized: 0.00 Dispensing Fee: 0.40 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 25115.96
---	--	--

Health Reimbursement Account: Benefits: 0.00 Member Access Fee: 0.00 Amount Used: 0.00 HRA Remaining Balance: 0.00	Miscellaneous Applied To Out of Pocket: 0.00 Applied To TROOP: 0.00 Applied To OOPM/MOOP: 0.00 Paid by Other Insurance: 0.00 Alternate Amount Paid: 0.00 Previous Amount Paid: 0.00 In Network Accumulation: 0.00 Out of Network Accumulation: 0.00
---	--

Med D Financials: LICs Paid by Plan: 5935.66 SPAP/Integrator Paid Amt: 0.00 Reported Gap Discount: 0.00 Deductible Gross Cost: 0.00 Deductible Plan Pay: 0.00 Initial Gross Cost: 3783.39 Initial Plan Pay: 2534.88 Gap Gross Cost: 3814.88 Gap Plan Pay: 0.00 Catastrophic Gross Cost: 17521.49 Catastrophic Plan Pay: 16645.42	
--	--

[View Settlement Codes](#) [View Comments](#) [Back](#)

Pharmacy Reimbursement

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

Reversal

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

[View Reimbursements](#)

Recipient

Name:
 Alternate Name:
 Address:
 City:
 State:
 Zip:

[Go to top](#)

EXHIBIT 47

Peoplesafe

Page 1 of 1

CAREMARK **PeopleSafe®** Close

Eligibility Maintenance ☐ Participant Inquiry ☐ Resolution Manager ☐ Medicare D Inquiry ☐ View Opportunities Tools: -- Select A Tool --

Client: **SILVERSCRIPT-INDIV-ENROLL** System: **RXCLAIM**

External ID: **[REDACTED]** Name: **[REDACTED]** Gndr: **F** Relationship: **MEMBER** Born: **1942** Effective: **01-01-2020** Expiration: **12-31-2039**

Navigation: [Main Screen](#) [Financial Details](#) [View Activity](#) [Prescription History](#) [Test Claims](#) [Plan Benefit Overview](#) [Account Balance](#) [Explanation of Benefits](#) [Transaction History](#) [Communication History](#) [Caremark.com](#)

Pharmacy Network: [Retail Transaction](#) [Plan Summary](#) [FSA/HSA/HRA History](#) [Coordination of Benefits](#) [Order Placement](#) [Adjustments](#) [Client Managed \(G & A\)](#) [View Triggers](#)

Prescription for: **[REDACTED]** MEMBER Delivery System: **POINT OF SALE** Dispense As Written: **0 - NO DAW**
 Prescription Number: **[REDACTED]** [Go to Reimbursement...](#) Pharmacy NPI: **[REDACTED]** Drug Price Type: **AVERAGE WHOLESALE PRICE**
 Drug NDC: **72626270101** Pharmacy NCPDP: **[REDACTED]** Drug Price Source: **MEDISPAN**
 Drug Name: **SCFOSBUWIR-VELPATASVIR** Pharmacy Name: **[REDACTED]** Pharmacy Claim Price Type: **[REDACTED]**

Participant Pay Participant Copay: 0.00 Initial Copay: 0.00 Gap Copay: 0.00 Catastrophic Copay: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 0.00	Client Pay Usual and Customary: 11520.00 Cost Submitted: 11520.00 Cost Allowed: 8064.00 Other Payer Recognized: 0.00 Dispensing Fee: 0.40 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 8064.40	Pharmacy Pay: Usual and Customary: 8064.00 Cost Allowed: 8064.00 Other Payer Recognized: 0.00 Dispensing Fee: 0.40 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 8064.40
---	--	---

Health Reimbursement Account:
 Benefits: 0.00
 Member Access Fee: 0.00
 Amount Used: 0.00
 HRA Remaining Balance: 0.00

Med D Financials:
 LICs Paid by Plan: 403.22
 SPAP/Integrator Paid Amt: 0.00
 Reported Gap Discount: 0.00
 Deductible Gross Cost: 0.00
 Deductible Plan Pay: 0.00
 Initial Gross Cost: 0.00
 Initial Plan Pay: 0.00
 Gap Gross Cost: 0.00
 Gap Plan Pay: 0.00
 Catastrophic Gross Cost: 8064.40
 Catastrophic Plan Pay: 7661.18

Miscellaneous
 Applied To Out of Pocket: 0.00
 Applied To TROOP: 0.00
 Applied To OOPM/MOOP: 0.00
 Paid by Other Insurance: 0.00
 Alternate Amount Paid: 0.00
 Previous Amount Paid: 0.00
 In Network Accumulation: 0.00
 Out of Network Accumulation: 0.00

[View Settlement Codes](#) [View Comments](#) [Back](#)

Pharmacy Reimbursement
 Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:
Reversal
 Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

[View Reimbursements](#)
Recipient
 Name:
 Alternate Name:
 Address:
 City:
 State:
 Zip:
[Go to top](#)

EXHIBIT 48



P.O. Box 30013, Pittsburgh, PA 15222-0330

March 20, 2019

[REDACTED]
[REDACTED] NJ [REDACTED]

**YOUR DRUG IS NOT ON OUR LIST OF COVERED DRUGS (FORMULARY)
OR IS SUBJECT TO CERTAIN LIMITS**

Dear [REDACTED]:

We want to tell you that SilverScript Choice (PDP) has provided you with a temporary supply of the following prescription: SOFOS/VELPAT TAB 400-100.

This drug is either not included on our list of covered drugs (called our formulary), or it's included on the formulary but subject to certain limits, as described in more detail later in this letter. SilverScript Choice (PDP) is required to provide you with a temporary supply of this drug. If your prescription is written for fewer than 30 days, we'll allow multiple fills to provide up to a maximum 30-day supply of medication.

It's important to understand that this is a temporary supply of this drug. Well before you run out of this drug, you should speak to SilverScript Choice (PDP) and/or the prescriber about:

- changing the drug to another drug that is on our formulary; or
- requesting approval for the drug by demonstrating that you meet our criteria for coverage; or
- requesting an exception from our criteria for coverage.

When you request approval for coverage or an exception from coverage criteria, these are called coverage determinations. Don't assume that any coverage determination, including any exception, you have requested or appealed has been approved just because you receive more fills of a drug. If we approve coverage, then we'll send you another written notice.

If you need assistance in requesting a coverage determination, including an exception, or if you want more information about when we will cover a temporary supply of a drug, contact us at 1-866-235-5660. TTY users should call 711. Live representatives are available 24 hours a day, 7 days a week. You can ask us for a coverage determination at any time. **Instructions on how to change your current prescription, how to ask for a coverage determination (including an exception), and how to appeal a denial if you disagree with our coverage determination are discussed at the end of this letter.**

The following is a specific explanation of why your drug is not covered or is limited.

Name of Drug: SOFOS/VELPAT TAB 400-100

Date Filled: 03/18/2019

Reason for Notification: This drug is not on our formulary. We will not continue to pay for this drug after you have received the maximum 30 days' temporary supply that we are required to cover unless you obtain a formulary exception from us.

How do I change my prescription?

If your drug is not on our formulary, or is on our formulary but we have placed a limit on it, you can ask us what other drug used to treat your medical condition is on our formulary, ask us to approve coverage by showing that you meet our criteria, or ask us for an exception. We encourage you to ask your prescriber if this other drug that we cover is an option for you. You have the right to request an exception from us to cover your drug that was originally prescribed. If you ask for an exception, your prescriber will need to provide us with a statement explaining why a prior authorization, quantity limit, or other limit we have placed on your drug is not medically appropriate for you.

How do I request a coverage determination, including an exception?

You or your prescriber may contact us to request a coverage determination, including an exception. The toll-free phone number is 1-866-235-5660 (TTY users should call 711), or you may fax to 1-855-633-7673, or you may write to us at: SilverScript Insurance Company Prescription Drug Plans Coverage Decisions and Appeals Department, P.O. Box 52000, MC 109, Phoenix, AZ 85072-2000. We are available 24 hours a day, 7 days a week.

If you are requesting coverage of a drug that is not on our formulary or an exception to a coverage rule, your prescriber must provide a statement supporting your request. It may be helpful to bring this notice with you to the prescriber or send a copy to his or her office. If the exception request involves a drug that is not on our formulary, the prescriber's statement must indicate that the requested drug is medically necessary for treating your condition because all of the drugs on our formulary would be less effective than the requested drug or would have adverse effects for you. If the exception request involves a prior authorization or other coverage rule we have placed on a drug that is on our formulary, the prescriber's statement must indicate that the coverage rule wouldn't be appropriate for you given your condition or would have adverse effects for you.

We must notify you of our decision no later than 24 hours, if the request has been expedited, or no later than 72 hours, if the request is a standard request, from when we receive your request. For exceptions, the timeframe begins when we obtain your prescriber's statement. Your request will be expedited if we determine, or your prescriber tells us, that your life, health, or ability to regain maximum function may be seriously jeopardized by waiting for a standard decision.

What if my request for coverage is denied?

If your request for coverage is denied, you have the right to appeal by asking for a review of the prior decision, which is called a redetermination. You must request this appeal within 60 calendar days from the date of our written decision on your coverage determination request. We accept standard and expedited requests by telephone and in writing. Contact us at: SilverScript Insurance Company Prescription Drug Plans Coverage Decisions and Appeals Department, P.O. Box 52000, MC 109, Phoenix, AZ 85072-2000; phone: 1-866-235-5660; TTY: 711; fax: 1-855-633-7673; 24 hours a day, 7 days a week.

If you need assistance in requesting a coverage determination, including an exception, or if you want more information about when we will cover a temporary supply of a drug, contact us at 1-866-235-5660, 24 hours a day, 7 days a week. TTY users should call 711. Live representatives are available 24 hours a day, 7 days a week. You can ask us for a coverage determination at any time. You can also visit our website at www.silverscript.com.

Sincerely,

SilverScript Choice (PDP)

The formulary may change at any time. You will receive notice when necessary.

Beneficiaries must use network pharmacies to access their prescription drug benefit.

ATENCIÓN: Si usted habla español, tenemos servicios de asistencia lingüística disponibles para usted sin costo alguno. Llame al 1-866-235-5660 (TTY: 711).

SilverScript is a Prescription Drug Plan with a Medicare contract offered by SilverScript Insurance Company. Enrollment in SilverScript depends on contract renewal.

SilverScript® Insurance Company complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. SilverScript Insurance Company does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

SilverScript Insurance Company:

- ξ Provides free aids and services to people with disabilities to communicate effectively with us, such as:
 - Written information in other formats (large print, audio, accessible electronic formats, other formats)

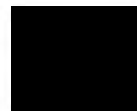
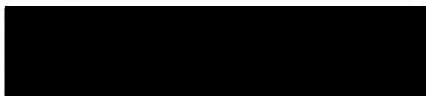
- ξ Provides free language services to people whose primary language is not English, such as:
 - Qualified interpreters
 - Information written in other languages

If you need written information in other formats or free language services, please contact Customer Care. This number can be found on the back of your member ID card or on the letter that accompanied this notice.

If you believe that SilverScript Insurance Company has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with: SilverScript Insurance Company, Grievance Department, P.O. Box 30016, Pittsburgh, PA 15222-0330. Fax: 1-866-217-3353.

You can file a grievance by mail, or by fax. If you need help filing a grievance, the SilverScript Grievance Department is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 1-800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.



ENGLISH

ATTENTION: If you speak English, language assistance services, free of charge, are available to you. Call 1-866-235-5660 (TTY*711).

SPANISH

ATENCIÓN: Si usted habla español, tenemos servicios de asistencia lingüística disponibles para usted sin costo alguno. Llame al 1-866-235-5660 (TTY: 711).

CHINESE

* * * * *
* * * * * 1-866-235-5660 (TTY:
711)*

VIETNAMESE

CHÚ Ý: Nếu quý vị nói tiếng Việt, thì có sẵn các dịch vụ trợ giúp ngôn ngữ miễn phí dành cho quý vị. Hãy gọi số 1-866-235-5660 (TTY: 711).

KOREAN

* * * * *
* * * * *
1-866-235-5660 (TTY: 711)* * * * *
* * * * *

TAGALOG

PANSININ: Kung nagsasalita po kayo ng Tagalog, magagamit ninyo ang mga serbisyong tulong sa wika ng walang bayad. Tawagan po ang *****235-5660 (TTY: 711).

RUSSIAN

ВНИМАНИЕ: Если вы говорите на русском языке, вам будут бесплатно предоставлены услуги переводчика. Звоните по телефону: 1-866-235-5660 (телетайп: 711).

ARABIC

ملاحظة: إذا كنت تتحدث العربية، تتوفر خدمات المساعدة اللغوية مجاناً. امن أهلك. اتصل بالرقم 1-866-235-5660 (الهاتف النصي: 711).

FRENCH CREOLE

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 1-866-235-5660 (TTY: 711).

FRENCH

ATTENTION : Si vous parlez français, des services gratuits d'interprétation sont à votre disposition. Veuillez appeler le 1-866-235-5660 (TTY: 711).

POLISH

UWAGA: Dla osób mówiących po polsku dostępna jest bezpłatna pomoc językowa. Zadzwoń pod numer 1-866-235-5660 (TTY: 711).

PORTUGUESE

ATENÇÃO: Se fala português, estão disponíveis serviços gratuitos de assistência linguística na sua língua. Telefone para 1-866-235-5660 (TTY: 711).

ITALIAN

ATTENZIONE: Se lei parla italiano, sono disponibili servizi gratuiti di assistenza linguistica nella sua lingua. Chiami 1-866-235-5660 (TTY: 711).

JAPANESE

* * * * *
* * * * *
* * * * * 1-866-235-5660 (TTY: 711) * *
* * * * *

GERMAN

BITTE BEACHTEN: Wenn Sie Deutsch sprechen, stehen Ihnen unsere Dolmetscher unter der Nummer 1-866-235-5660 (TTY: 711) kostenlos zur Verfügung.

FARSI

توجه: چنانچه به زبان فارسی صحبت می کنید، خدمات کمک زبانی، به صوار تریگا رد، نختیار شما قرارا خواهاد گرفت. با شماره 1-866-235-5660 (TTY: 711) تماس بگیرید.

EXHIBIT 49



**Redetermination Notice
Denial of Medicare Prescription Drug Coverage**



[Redacted] NJ [Redacted]

Date: 04/16/2019

Enrollee Name: [Redacted]
Plan Name: SilverScript Choice (PDP)
Formulary ID: 00019295

Enrollee's Medicare (HIC) Number: [Redacted]
Contract ID: [Redacted]
Plan ID: 008

We agree with our initial coverage determination and are denying the following prescription drug(s) that you or your physician or other prescriber requested: SOFOSBUVIR/VELPATASVIR Tablet

We denied this request because: Your Medicare Part D drug plan was asked to cover a drug that is not on the formulary (this is called a formulary exception). The generic drug you requested sofosbuvir/velpatasvir is not on your plan's formulary (list of covered drugs). Your plan covers the Brand version of this drug, Epclusa.

Both the brand Epclusa and generic version of this drug sofosbuvir/velpatasvir would be expected to have the same effectiveness in treating your condition. The brand drug on the formulary and its generic contain the same active medications. They both contain the same inactive ingredients such as dyes, and would be expected to have the same risk of causing adverse effects (side effects). Talk to your prescriber to see if any of the formulary alternative(s) would be right for you.

Additional formulary alternatives that may be an appropriate choice for you are:

Harvoni tablets (requires prior authorization)
Mavyret tablets (requires prior authorization)
Vosevi tablets (requires prior authorization)
Zepatier tablets (requires prior authorization)

What If I Don't Agree With This Decision?

You have the right to ask for an independent review (appeal) of our decision. If your case involves



an exception request and your physician or other prescriber did not already provide your plan with a statement supporting your request, **your physician or other prescriber must provide a statement to support your exception request and you should attach a copy of this statement to your appeal request.** If you want to appeal our decision, you must request your appeal in writing within 60 calendar days after the date of this notice. You must mail or fax your written request to the independent reviewer at:

Requests from PDP and MA-PD Plans:

MAXIMUS Federal Services
3750 Monroe Ave., Suite #703
Pittsford, NY 14534-1302

Customer Service:

Toll-free: (877) 456-5302

Fax Numbers:

Toll-free: (866) 825-9507
(585) 425-5301

Who May Request an Appeal?

You, your prescriber, or someone you name to act for you (your **representative**) may request an appeal. You can name a relative, friend, advocate, attorney, doctor, or someone else to act for you. An Appointment of Representation is not needed if the person appealing is your prescriber or is authorized under State law to act for you (for example, through a health care power of attorney or health care proxy).

You can call us at: 1-866-235-5660, 24 hours a day, 7 days a week, to learn how to name your representative. If you have a hearing or speech impairment, please call us at TTY: 711.

SilverScript is a Prescription Drug Plan with a Medicare contract offered by SilverScript Insurance Company. Enrollment in SilverScript depends on contract renewal.

ATENCIÓN: Si usted habla español, tenemos servicios de asistencia lingüística disponibles para usted sin costo alguno. Llame al 1-866-235-5660 (TTY: 711).

The formulary may change at any time. You will receive notice when necessary.

IMPORTANT INFORMATION ABOUT YOUR APPEAL RIGHTS

For more information about your appeal rights, call us or see your Evidence of Coverage

There Are Two Kinds of Appeals You Can Request

Expedited (72 hours) - You can request an expedited (fast) appeal for cases that involve coverage, if you or your doctor believes that your health could be seriously harmed by waiting up to 7 days for a decision. If your request to expedite is granted, the independent reviewer must give you a decision no later than 72 hours after receiving your appeal (the time frame may be extended in limited circumstances).

- **If the doctor who prescribed the drug(s) asks for an expedited appeal for you, or supports you in asking for one, and the doctor indicates that waiting for 7 days could seriously harm your health, the independent reviewer will automatically expedite the appeal.**
- If you ask for an expedited appeal without support from a doctor, the independent reviewer will decide if your health requires an expedited appeal. If you do not get an expedited appeal, your appeal will be decided within 7 days.
- Your appeal will not be expedited if you've already received the drug you are appealing.

Standard (7 days) - You can request a standard appeal for a case involving coverage or payment. The independent reviewer must give you a decision no later than 7 days after receiving your appeal (the time frame may be extended in limited circumstances).

When the Independent Reviewer Can Extend the Time Frame for Making a Decision – The time frame may be extended if your case involves an exception request and we have not received the supporting statement from your doctor or other prescriber supporting the request. The time frame also may be extended when the person acting for you files an appeal request but does not submit proper documentation of representation. In both situations, the independent reviewer may toll (or stop the clock) for up to 14 days to get this information.

What Do I Include with My Appeal?

You should include your name, address, HIC number, the reasons for appealing, and any evidence you wish to attach. If the appeal is

made by someone other than you or your doctor or other prescriber, the person must submit a document appointing him or her to act for you.

If your appeal relates to a decision by us to deny a drug that is not on our list of covered drugs (formulary) or if you are asking for an exception to a prior authorization (PA) or other utilization management (UM) requirement, your prescribing doctor or other prescriber must submit a statement with your appeal request indicating that all the drugs on any tier of our formulary (or the PA/UM requirement) would not be as effective to treat your condition as the requested drug or would harm your health.

How Do I Request an Appeal?

You, your prescriber or your representative should mail or fax your written appeal request to:

MAXIMUS Federal Services
3750 Monroe Ave., Suite #703
Pittsford, NY 14534-1302
Fax: (585) 425-5301
Toll free fax: (866) 825-9507

What Happens Next? If you appeal, the independent reviewer will review your case and give you a decision. If any of the prescription drugs you requested are still denied, you can appeal to an administrative law judge (ALJ) if the value of your appeal is at least \$160. If you disagree with the ALJ decision, you will have the right to further appeal. You will be notified of your appeal rights if this happens.

Contact Information:


If you need information or help, call us at:
Toll Free: 1-866-235-5660
24 hours a day, 7 days a week
TTY: 711

Other Resources To Help You:

Medicare Rights Center
Toll Free: 1-888-HMO-9050
Elder Care Locator
Toll Free: 1-800-677-1116
1-800-MEDICARE (1-800-633-4227)
TTY: 1-877-486-2048
24 hours a day, 7 days a week

SilverScript®

Plan Name: SilverScript Choice (PDP)
Formulary ID: 00019295

Contract ID: 
Plan ID: 008

Request for Reconsideration of Medicare Prescription Drug Denial

Because your Medicare drug plan has upheld its initial decision to deny coverage of, or payment for, a prescription drug you requested, you have the right to ask for an independent review of the plan's decision. **You may use this form to request an independent review of your drug plan's decision.** You have 60 days from the date of the plan's Redetermination Notice to ask for an independent review. Please complete this form and mail or fax it to:

Requests from PDP and MA-PD Plans:

MAXIMUS, Federal Services
3750 Monroe Ave., Suite #703
Pittsford, NY 14534-1302

Customer Service:

Toll-free: (877) 456-5302

Fax Numbers:

Toll-free: (866) 825-9507
(585) 425-5301

Note about Representatives: Your prescriber may file a reconsideration request on your behalf without being an appointed representative. If you want another individual, such as a family member or friend, to request an independent review for you, that individual must be your representative. Contact your Medicare drug plan to learn how to name a representative.

Enrollee's Information

Enrollee's Name _____ Date of Birth _____

Enrollee's Address _____

City _____ State _____ Zip Code _____

Phone () _____

Enrollee's Medicare (HIC) Number (as shown on your Medicare card) _____

Complete the following section ONLY if the person making this request is not the enrollee or the enrollee's prescriber (make sure to attach documentation showing the person's authority to represent enrollee for purposes of this request):



Requestor's Name _____
Requestor's Relationship to Enrollee _____
Address _____
City _____ State _____ Zip Code _____
Phone () _____

Representation documentation for appeal requests made by someone other than enrollee or prescriber:

Attach documentation showing the authority to represent the enrollee (a completed Form CMS-1696 or a written equivalent) if it was not submitted at the coverage determination or redetermination level. A physician or other prescriber may request an appeal on behalf of an enrollee without being an appointed representative.

Prescription drug you asked your plan to cover: _____

Prescribing Physician's Information

Name _____

Address _____

City _____ State _____ Zip Code _____

Office Phone: () _____ Fax: () _____

Office Contact Person _____

Expedited Decisions

If you or your prescribing physician or other prescriber believe that waiting for a standard decision (which will be provided within 7 days) could seriously harm your life, health, or ability to regain maximum function, you can ask for an expedited (fast) decision. If your prescribing physician or other prescriber indicates that waiting 7 days could seriously harm your life or health or ability to regain maximum function, the independent review organization will automatically give you a decision within 72 hours. This timeframe may be extended for up to 14 calendar days if your case involves an exception request and we have not received the supporting statement from your doctor or other prescriber supporting the request, OR the person acting for you files an appeal request but does not submit proper documentation of representation. If you do not obtain your physician's or other prescriber's support for an expedited appeal, the independent review organization will decide if your health condition requires a fast decision.

- ☐ Check this box if you believe you need a decision within 72 hours (if you have a supporting statement from your prescribing physician, attach it to this request).

Please attach any additional information you have related to your appeal such as a statement from your prescribing physician or other prescriber and relevant medical records.

Additional information we should consider:



Important: Please include a copy of the Redetermination (denial) Notice you received from your drug plan with this request.

Signature of person requesting the appeal (the enrollee or the representative):

_____ Date: _____

SilverScript is a Prescription Drug Plan with a Medicare contract offered by SilverScript Insurance Company. Enrollment in SilverScript depends on contract renewal.

ATENCIÓN: Si usted habla español, tenemos servicios de asistencia lingüística disponibles para usted sin costo alguno. Llame al 1-866-235-5660 (TTY: 711).

The formulary may change at any time. You will receive notice when necessary.

EXHIBIT 50

Peoplesafe

Page 1 of 1

CAREMARK **PeopleSafe®** Close

Eligibility Maintenance ☐ Participant Inquiry ☐ Resolution Manager ☐ Medicare Inquiry ☐ View Opportunities Tools: -- Select A Tool --

Client: **SILVERSCRIPT-INDIV-ENROLL** System: **RXCLAIM**

External ID: **[REDACTED]** Name: **[REDACTED]** Gndr: **F** Relationship: **MEMBER** Born: **[REDACTED] 1942** Effective: **01-01-2020** Expiration: **12-31-2039**

[Main Screen](#) [Financial Details](#) [View Activity](#) [Prescription History](#) [Test Claims](#) [Plan Benefit Overview](#) [Account Balance](#) [Explanation of Benefits](#) [Transaction History](#) [Communication History](#) [Caremark.com](#)

[Pharmacy Network](#) [Retail Transactions](#) [Plan Summary](#) [FSA/HSA/HRA History](#) [Coordination of Benefits](#) [Order Placement](#) [Adjustments](#) [Client Managed \(G & A\)](#) [View Triggers](#)

Prescription for: **[REDACTED] MEMBER** Delivery System: **POINT OF SALE** Dispense As Written: **0 - NO DAW**
 Prescription Number: **[REDACTED]** [Go to Reimbursement...](#) Pharmacy NPI: **[REDACTED]** Drug Price Type: **AVERAGE WHOLESALE PRICE**
 Drug NDC: **61958220101** Pharmacy NCPDP: **[REDACTED]** Drug Price Source: **MEDISPAN**
 Drug Name: **EPLUSIA** Pharmacy Name: **[REDACTED]** Client Claim Price Type: **[REDACTED]** Pharmacy Claim Price Type: **[REDACTED]**

Participant Pay Participant Copay: 0.00 Initial Copay: 0.00 Gap Copay: 0.00 Catastrophic Copay: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 0.00	Client Pay Usual and Customary: 35884.80 Cost Submitted: 25119.36 Cost Allowed: 0.00 Other Payer Recognized: 0.40 Dispensing Fee: 0.00 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 25119.76	Pharmacy Pay: Usual and Customary: 25119.36 Cost Allowed: 0.00 Other Payer Recognized: 0.40 Dispensing Fee: 0.00 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 25119.76
---	--	--

Health Reimbursement Account:
 Benefits: 0.00
 Member Access Fee: 0.00
 Amount Used: 0.00
 HRA Remaining Balance: 0.00

Med D Financials:
 LICs Paid by Plan: 1255.98
 SPAP/Integrator Paid Amt: 0.00
 Reported Gap Discount: 0.00
 Deductible Gross Cost: 0.00
 Deductible Plan Pay: 0.00
 Initial Gross Cost: 0.00
 Initial Plan Pay: 0.00
 Gap Gross Cost: 0.00
 Gap Plan Pay: 0.00
 Catastrophic Gross Cost: 25119.76
 Catastrophic Plan Pay: 23863.78

[View Settlement Codes](#) [View Comments](#) [Back](#)

Pharmacy Reimbursement

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

Reversal

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

[View Reimbursements](#)

Recipient

Name:
 Alternate Name:
 Address:
 City:
 State:
 Zip:

[Go to top](#)

EXHIBIT 51

Peoplesafe

Page 1 of 1

CAREMARK **PeopleSafe®** Close

Eligibility Maintenance ☐ Participant Inquiry ☐ Resolution Manager ☐ Medicare D Inquiry ☐ View Opportunities Tools: -- Select A Tool --

Client: [REDACTED] SILVERSCRIPT-INDIV-ENROLL System: RXCLAIM

External ID: [REDACTED] Name: [REDACTED] Gndr: F Relationship: MEMBER Born: [REDACTED] 1936 Effective: 01-01-2020 Expiration: 12-31-2039

[Main Screen](#) [View Activity](#) [Prescription History](#) [Test Claim](#) [Plan Benefit Override](#) [Account Balance](#) [Explanation of Benefits](#) [Transaction History](#) [Communication History](#) [Caremark.com](#)
[Pharmacy Network](#) [Retail Transaction](#) [Plan Summary](#) [FSA/HSA/HRA History](#) [Coordination of Benefits](#) [Order Placement](#) [Adjustments](#) [Client Managed G & A](#) [View Triggers](#)

Prescription for: [REDACTED] UNKNOWN CLAIM INFORMATION ONLY

Origin: 1 - Written Received: 01-14-2019 Kit Type:
 Number-Partial / Fill: [REDACTED] Filled: 01-14-2019 Kit Copay Bypass:
 Claim / Sequence: [REDACTED] Controlled Substance: NOT APPLICABLE Compound: N - NO
 Override Type/Id: [REDACTED] Status: [Rejected 01-14-2019 06:33:40 PM](#)
 1 - Member PA/ 2223333444 Multiple PA's:

Drug

Dispensed Drug: SCFOSBUVIR-VELPATASVIR--400-100MG	Prescribed Quantity:	Unit Per Dose:
Dispensed ID: [REDACTED]	Dispensed Day Supply: 28	Dose Per Day:
Prescriber Name: [REDACTED]	Dispensed Quantity: 28,000	Drug Type: BRAND
Pharmacy Name: [REDACTED]	Covered Day Supply:	Dispense as Written: 0 - NO DAY
Ingredient Name:	Covered Quantity:	GPI: 12359902650330
	Formulary Preference: Non-Formulary	Formulary Tier: 4

Reject Codes	Reject Description	Settlement Codes	Settlement Description
569	PROVIDE NOTICE: MEDICARE PRESCRIPTION DRUG COVERAGE AND YOUR RIGHTS		DISPENSE BRAND EPCLUSA
70	NDC/PRODUCT/SERVICE NOT COVERED	10500	COB DATA FROM MBI/HICN LINKAGE TABLE

General [Show](#)

Medicare Part D [Show](#)

View Financials	View Comments	View Transmission	View Drug Limitations	View PBO	Populate Test Claim	Back
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Capture Activity

EXHIBIT 52

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Important: This notice explains your right to appeal our decision. Read this notice carefully. If you need help, you can call one of the numbers listed on the last page under "Get help & more information."



P.O. Box 30003, Pittsburgh, PA 15222-0330
1-866-235-5660

NOTICE OF DENIAL OF MEDICARE PART D PRESCRIPTION DRUG COVERAGE

Date: 01/15/2019	
Enrollee's Name: [REDACTED]	Member Number: [REDACTED]
<p>Your request was denied We have denied coverage or payment under your Medicare Part D benefit for the following prescription drug(s) that you or your prescriber requested: SOFOSBUVIR/VELPATASVIR Tablet</p> <p>Why did we deny your request? We denied this request under Medicare Part D because: Your Medicare Part D drug plan was asked to cover a drug that is not on the formulary (this is called a formulary exception). The generic drug you requested sofosbuvir/velpatasvir is not on your plan's formulary (list of covered drugs). Your plan covers the Brand version of this drug, Epclusa.</p> <p>Both the brand Epclusa and generic version of this drug sofosbuvir/velpatasvir would be expected to have the same effectiveness in treating your condition. The brand drug on the formulary and its generic contain the same active medications. They both contain the same inactive ingredients such as dyes, and would be expected to have the same risk of causing adverse effects (side effects). Talk to your prescriber to see if any of the formulary alternative(s) would be right for you.</p> <p>Additional formulary alternatives that may be an appropriate choice for you are Harvoni (brand) (prior authorization required), Zepatier (prior authorization required), Epclusa (brand) (prior authorization required), Vosevi (prior authorization required), Mavyret Tablet (prior authorization required).</p> <p>You should share a copy of this decision with your prescriber so you and your prescriber can discuss next steps. If your prescriber requested coverage on your behalf, we have shared this decision with your prescriber.</p>	

What If I Don't Agree With This Decision?

You have the right to appeal. If you want to appeal, you must request your appeal within 60 calendar days after the date of this notice. We can give you more time if you have a good reason for missing the deadline. You have the right to ask us for a **formulary exception** if you believe you need a drug that is not on our list of covered drugs (formulary). You have the right to ask us for a **coverage rule exception** if you believe a rule such as prior authorization or a quantity limit should not apply to you. You can either provide information that shows that you meet the coverage rule that applies to the drug you are

Form CMS-10146

(Expires 02/29/2020)

requesting or you can ask for a coverage rule exception. You can ask for a **tiering exception** if you believe you should get a drug at a lower cost-sharing amount. Your prescriber must provide a statement to support your exception request.

Who May Request an Appeal?

You, your prescriber, or your representative may request an expedited (fast) or standard appeal. You can name a relative, friend, advocate, attorney, doctor, or someone else to be your representative. Others may already be authorized under State law to be your representative.

You can call us at: 1-866-235-5660 to learn how to appoint a representative. If you have a hearing or speech impairment, please call us at TTY: 711.

IMPORTANT INFORMATION ABOUT YOUR APPEAL RIGHTS

There Are Two Kinds of Appeals You Can Request

Expedited (72 hours): You, your prescriber, or your representative can request an expedited (fast) appeal if you or your prescriber believe that your health could be seriously harmed by waiting up to 7 days for a decision. You cannot request an expedited appeal if you are asking us to pay you back for a prescription drug you already received. If your request to expedite is granted, we must give you a decision no later than 72 hours after we get your appeal.

- * **If your prescriber** asks for an expedited appeal for you, or supports you in asking for one, and indicates that waiting for 7 days could seriously harm your health, **we will automatically expedite your appeal.**
- * If you ask for an expedited appeal without support from your prescriber, we will decide if your health requires an expedited appeal. We will notify you if we do not give you an expedited appeal and we will decide your appeal within 7 days.

Standard (7 days): You, your prescriber, or your representative can request a standard appeal. We must give you a decision no later than 7 days after we get your appeal.

What Do I Include with My Appeal Request?

You should include your name, address, Member number, the reasons for appealing, and any evidence you wish to attach. Remember, your doctor must provide us with a supporting statement if you're requesting an exception to a coverage rule. You should include information about why the coverage rule should not apply to you because of your specific medical condition. If your appeal relates to a decision by us to deny a drug that is not on our formulary, your prescriber must indicate that all the drugs on any tier of our formulary would not be as effective to treat your condition as the requested off-formulary drug or would harm your health.

How Do I Request an Appeal?

For an Expedited Appeal: You, your prescriber, or your representative should contact us by telephone or fax at the numbers below:

Phone: 1-866-235-5660
TTY: 711
Fax: 1-855-633-7673

For a Standard Appeal: You, your prescriber, or your representative should mail or deliver your written appeal request to the address below:

CVS Caremark Part D Appeals and Exceptions
P.O. Box 52000, MC109
Phoenix, AZ 85072-2000
Phone: 1-866-235-5660
TTY: 711

What Happens Next?

If you appeal, we will review your case and give you a decision. If any of the prescription drugs you requested are still denied, you can request an independent review of your case by a reviewer outside of your Medicare Drug Plan. If you disagree with that decision, you will have the right to further appeal. You will be notified of your appeal rights if this happens.

Get help & more information

- SilverScript Choice (PDP) Toll Free: 1-866-235-5660
TTY users call: 711
24 hours a day, 7 days a week
www.silverscript.com
- 1-800-MEDICARE (1-800-633-4227), 24 hours, 7 days a week. TTY users call: 1-877-486-2048
- Medicare Rights Center: 1-888-HMO-9050
- Elder Care Locator: 1-800-677-1116
- State Health Insurance Program National Technical Assistance Center: 877-839-2675

PRA Disclosure Statement According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection is 0938-0976. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, and gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

CMS does not discriminate in its programs and activities: To request this form in an accessible format (e.g., Braille, Large Print, Audio CD) contact your Medicare Drug Plan. If you need assistance contacting your plan, call: 1-800-MEDICARE.



Request for Redetermination of Medicare Prescription Drug Denial

Because we, SilverScript Choice (PDP), denied your request for coverage of (or payment for) a prescription drug, you have the right to ask us for a redetermination (appeal) of our decision. You have 60 days from the date of our Notice of Denial of Medicare Prescription Drug Coverage to ask us for a redetermination. This form may be sent to us by mail or fax:

Address:	Fax Number:
CVS Caremark Part D Appeals and Exceptions	1-855-633-7673
P.O. Box 52000, MC109	
Phoenix, AZ 85072-2000	

You may also ask us for an appeal through our website at www.silverscript.com. Expedited appeal requests can be made by phone at 1-866-235-5660, TTY: 711, 24 hours a day, 7 days a week.

Who May Make a Request: Your prescriber may ask us for an appeal on your behalf. If you want another individual (such as a family member or friend) to request an appeal for you, that individual must be your representative. Contact us to learn how to name a representative.

Enrollee's Information		
Enrollee's Name _____		Date of Birth _____
Enrollee's Address _____		
City _____	State _____	Zip Code _____
Phone _____		Enrollee's Plan ID Number _____
Complete the following section ONLY if the person making this request is not the enrollee:		
Requestor's Name _____		
Requestor's Relationship to Enrollee _____		
Address _____		
City _____	State _____	Zip Code _____
Phone _____		
<u>Representation documentation for appeal requests made by someone other than enrollee or the enrollee's prescriber:</u>		
<p>Attach documentation showing the authority to represent the enrollee (a completed Authorization of Representation Form CMS-1696 or a written equivalent) if it was not submitted at the coverage determination level. For more information on appointing a representative, contact your plan or 1-800-Medicare, 24 hours a day, 7 days a week. TTY users call: 1-877-486-2048</p>		

Prescription drug you are requesting:

Name of drug: _____ Strength/quantity/dose: _____

Have you purchased the drug pending appeal? ☐ Yes ☐ No

If "Yes": Date purchased: _____ Amount paid: \$ _____ (attach copy of receipt)

Name and telephone number of pharmacy: _____

Prescriber's Information

Name _____

Address _____

City _____ State _____ Zip Code _____

Office Phone _____ Fax _____

Office Contact Person _____

Important Note: Expedited Decisions

If you or your prescriber believe that waiting 7 days for a standard decision could seriously harm your life, health, or ability to regain maximum function, you can ask for an expedited (fast) decision. If your prescriber indicates that waiting 7 days could seriously harm your health, we will automatically give you a decision within 72 hours. If you do not obtain your prescriber's support for an expedited appeal, we will decide if your case requires a fast decision. You cannot request an expedited appeal if you are asking us to pay you back for a drug you already received.

☐ **CHECK THIS BOX IF YOU BELIEVE YOU NEED A DECISION WITHIN 72 HOURS****(If you have a supporting statement from your prescriber, attach it to this request.)**

Please explain your reasons for appealing. Attach additional pages, if necessary. Attach any additional information you believe may help your case, such as a statement from your prescriber and relevant medical records. You may want to refer to the explanation we provided in the Notice of Denial of Medicare Prescription Drug Coverage.

Signature of person requesting the appeal (the enrollee, or the enrollee's prescriber or representative):**Date:** _____

SilverScript is a Prescription Drug Plan with a Medicare contract offered by SilverScript Insurance Company. Enrollment in SilverScript depends on contract renewal.

ATENCIÓN: Si usted habla español, tenemos servicios de asistencia lingüística disponibles para usted

sin costo alguno. Llame al 1-866-235-5660 (TTY: 711).

The formulary may change at any time. You will receive notice when necessary.

EXHIBIT 53

Peoplesafe

Page 1 of 1

CAREMARK **PeopleSafe®** Close

Eligibility Maintenance **Participant Inquiry** Resolution Manager Medicare D Inquiry View Opportunities Tools: -- Select A Tool --

Client: **SILVERSCRIPT-INDIV-ENROLL** System: **RXCLAIM**

External ID: **[REDACTED]** Name: **[REDACTED]** Gndr: **F** Relationship: **MEMBER** Born: **[REDACTED] 1936** Effective: **01-01-2020** Expiration: **12-31-2039**

Main Screen Financial Details View Activity Prescription History Test Claims **Plan Benefit Overview** Account Balance Explanation of Benefits Transaction History Communication History Caremark.com

Pharmacy Network Retail Transaction Plan Summary FSA/HSA/HRA History Coordination of Benefits Order Placement Adjustments Client Managed G & A **View Triggers**

Prescription for: **[REDACTED] UNKNOWN** Delivery System: **POINT OF SALE** Dispense As Written: **0 - NO DAW**
 Prescription Number: **[REDACTED]** [Go to Reimbursement...](#) Pharmacy NPI: **[REDACTED]** Drug Price Type: **AVERAGE WHOLESALE PRICE**
 Drug NDC: **61958220101** Pharmacy NCPDP: **[REDACTED]** Drug Price Source: **MEDISPAN**
 Drug Name: **EPLUSA** Pharmacy Name: **[REDACTED]** Client Claim Price Type: **[REDACTED]** Pharmacy Claim Price Type: **[REDACTED]**

Participant Pay Participant Copay: 3.80 Initial Copay: 922.71 Gap Copay: 3772.08 Catastrophic Copay: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 3.80	Client Pay Usual and Customary: 29904.00 Cost Submitted: 25119.36 Cost Allowed: 25119.36 Other Payer Recognized: 0.00 Dispensing Fee: 0.40 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 25115.96	Pharmacy Pay: Usual and Customary: 25119.36 Cost Allowed: 25119.36 Other Payer Recognized: 0.00 Dispensing Fee: 0.40 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 25115.96
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Health Reimbursement Account: Benefits: 0.00 Member Access Fee: 0.00 Amount Used: 0.00 HRA Remaining Balance: 0.00	Miscellaneous Applied To Out of Pocket: 0.00 Applied To TROOP: 0.00 Applied To OOPM/MOOP: 0.00 Paid by Other Insurance: 0.00 Alternate Amount Paid: 0.00 Previous Amount Paid: 0.00 In Network Accumulation: 0.00 Out of Network Accumulation: 0.00
---	--

Med D Financials: LICs Paid by Plan: 5618.56 SPAP/Integrator Paid Amt: 0.00 Reported Gap Discount: 0.00 Deductible Gross Cost: 0.00 Deductible Plan Pay: 0.00 Initial Gross Cost: 2796.12 Initial Plan Pay: 1873.41 Gap Gross Cost: 3772.08 Gap Plan Pay: 0.00 Catastrophic Gross Cost: 18551.56 Catastrophic Plan Pay: 17623.99	
--	--

View Settlement Codes View Comments Back

Pharmacy Reimbursement

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

Reversal

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

[View Reimbursements](#)

Recipient

Name:
 Alternate Name:
 Address:
 City:
 State:
 Zip:

[Go to top](#)

EXHIBIT 54

Peoplesafe

Page 1 of 1

CAREMARK **PeopleSafe®** Close

Eligibility Maintenance ☐ Participant Inquiry ☐ Resolution Manager ☐ Medicare D Inquiry ☐ View Opportunities Tools: -- Select A Tool --

Client: **SILVERSCRIPT-INDIV-ENROLL** System: **RXCLAIM**

External ID: **[REDACTED]** Name: **[REDACTED]** Gndr: **F** Relationship: **MEMBER** Born: **[REDACTED] 1936** Effective: **01-01-2020** Expiration: **12-31-2039**

[Main Screen](#) [Financial Details](#) [View Activity](#) [Prescription History](#) [Test Claims](#) [Plan Benefit Overview](#) [Account Balance](#) [Explanation of Benefits](#) [Transaction History](#) [Communication History](#) [Caremark.com](#)

[Pharmacy Network](#) [Retail Transaction](#) [Plan Summary](#) [FSA/HSA/HRA History](#) [Coordination of Benefits](#) [Order Placement](#) [Adjustments](#) [Client Managed G & A](#) [View Triggers](#)

Prescription for: **[REDACTED] UNKNOWN** Delivery System: **POINT OF SALE** Dispense As Written: **0 - NO DAW**
 Prescription Number: **[REDACTED]** [Go to Reimbursement...](#) Pharmacy NPI: **[REDACTED]** Drug Price Type: **AVERAGE WHOLESALE PRICE**
 Drug NDC: **61958220101** Pharmacy NCPDP: **[REDACTED]** Drug Price Source: **MEDISPAN**
 Drug Name: **EPLUSA** Pharmacy Name: **[REDACTED]** Client Claim Price Type: **[REDACTED]** Pharmacy Claim Price Type: **[REDACTED]**

Participant Pay Participant Copay: 0.00 Initial Copay: 0.00 Gap Copay: 0.00 Catastrophic Copay: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 0.00	Client Pay Usual and Customary: 29904.00 Cost Submitted: 25119.36 Cost Allowed: 25119.36 Other Payer Recognized: 0.00 Dispensing Fee: 0.40 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 25119.76	Pharmacy Pay: Usual and Customary: 25119.36 Cost Allowed: 25119.36 Other Payer Recognized: 0.00 Dispensing Fee: 0.40 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 25119.76
---	--	--

Health Reimbursement Account:
 Benefits: 0.00
 Member Access Fee: 0.00
 Amount Used: 0.00
 HRA Remaining Balance: 0.00

Med D Financials:
 LICs Paid by Plan: 1255.98
 SPAP/Integrator Paid Amt: 0.00
 Reported Gap Discount: 0.00
 Deductible Gross Cost: 0.00
 Deductible Plan Pay: 0.00
 Initial Gross Cost: 0.00
 Initial Plan Pay: 0.00
 Gap Gross Cost: 0.00
 Gap Plan Pay: 0.00
 Catastrophic Gross Cost: 25119.76
 Catastrophic Plan Pay: 23863.78

Miscellaneous
 Applied To Out of Pocket: 0.00
 Applied To TROOP: 0.00
 Applied To OOPM/MOOP: 0.00
 Paid by Other Insurance: 0.00
 Alternate Amount Paid: 0.00
 Previous Amount Paid: 0.00
 In Network Accumulation: 0.00
 Out of Network Accumulation: 0.00

[View Settlement Codes](#) [View Comments](#) [Back](#)

Pharmacy Reimbursement
 Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:
Reversal
 Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

[View Reimbursements](#)
Recipient
 Name:
 Alternate Name:
 Address:
 City:
 State:
 Zip:
[Go to top](#)

EXHIBIT 55

SilverScript Choice (PDP) is operated by
SilverScript Insurance Company
P.O. Box 30003
Pittsburgh, PA 15222-0330

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SilverScript®

[REDACTED]
CA [REDACTED]

02/07/2019

Your member numbers are:

Member ID: [REDACTED]

Rx PCN: [REDACTED]

Your Monthly Prescription Drug Summary

For January, 2019

This summary is your "Explanation of Benefits" (EOB) for your Medicare prescription drug coverage (Part D). Please review this summary and keep it for your records. (This is not a bill.)

Here are the sections in this summary:

SECTION 1. Your prescriptions during the past month

SECTION 2. Which "drug payment stage" are you in?

SECTION 3. Your "out-of-pocket costs" and "total drug costs" (amounts and definitions)

SECTION 4. Updates to the plan's Drug List that affect drugs you take

SECTION 5. If you see mistakes on this summary or have questions, what should you do?

SECTION 6. Important things to know about your drug coverage and your rights

Need large print or another format?

To get this material in other formats, or ask for language translation services, call SilverScript Choice (PDP) Customer Care (the number is on this page).

For languages other than English:

Español: 1-866-235-5660

Other language: 1-866-235-5660

SilverScript Choice (PDP) Customer Care

If you have questions or need help, call us 24 hours a day, 7 days a week. Calls to these numbers are free.

1-866-235-5660

TTY users call: 711

On the web at: www.silverscript.com

SilverScript is a Prescription Drug Plan with a Medicare contract offered by SilverScript Insurance Company. Enrollment in SilverScript depends on contract renewal.

[REDACTED]

2

SECTION 1. Your prescriptions during the past month

- Chart 1 shows your prescriptions for covered Part D drugs for the past month.
- Please look over this information about your prescriptions to be sure it is correct. If you have any questions or think there is a mistake, Section 5 tells what you should do.

CHART 1.

Your prescriptions for covered Part D drugs
January, 2019

	Plan paid	You paid	Other payments (made by programs or organizations; see Section 3)
IRBESARTAN TAB 300MG 01/07/2019 MAICO PHARMACY	\$0.00	\$1.25	\$38.47 (paid by "Extra Help")
OLOPATADINE SOL 0.2% 01/07/2019 MAICO PHARMACY	\$58.34	\$1.25	\$57.09 (paid by "Extra Help")
XIIIDRA DRO 5% 01/07/2019 MAICO PHARMACY	\$256.39	\$3.80	\$252.58 (paid by "Extra Help")
FLUTICASONE SPR 50MCG 01/08/2019 MAICO PHARMACY	\$0.00	\$1.25	\$2.52 (paid by "Extra Help")
SYMBICORT AER 160-4.5 01/08/2019 MAICO PHARMACY	\$303.94	\$3.80	\$43.20 (paid by "Extra Help")
EPCLUSA TAB 400- 100 01/16/2019 E-Z CARE PHARMACY	\$19,497.40	\$3.80	\$5,618.56 (paid by "Extra Help")
LEVOCETIRIZI TAB 5MG 01/21/2019 MAICO PHARMACY	\$8.08	\$0.00	\$3.40 (paid by "Extra Help")

continue

3

CHART 1.
Your prescriptions for covered Part D drugs
January, 2019

	Plan paid	You paid	Other payments (made by programs or organizations; see Section 3.)
TOTALS for the month of: January, 2019	\$20,124.15 (total for the month)	\$15.15 (total for the month)	\$6,015.82 (total for the month)
Your "out-of-pocket costs" amount is \$5,100.00. (This is the amount you paid this month (\$15.15) plus the amount of "other payments" made this month that count toward your "out-of-pocket costs" (\$5,084.85). See definitions in Section 3.)			(Of this amount, \$5,084.85 counts toward your "out-of-pocket costs." See definitions in Section 3.)
Your "total drug costs" amount is \$26,155.12. (This is the total for this month of all payments made for your drugs by the plan (\$20,124.15) and you (\$15.15) plus "other payments" (\$6,015.82).)			

Year - to - date totals 01/01/2019 through 01/31/2019			
	Plan paid	You paid	Other payments (made by programs or organizations; see Section 3.)
Your year - to - date amount for "out-of-pocket costs" is \$5,100.00.	\$20,124.15 (year - to - date total)	\$15.15 (year - to - date total)	\$6,015.82 (year - to - date total)
Your year - to - date amount for "total drug costs" is \$26,155.12. For more about "out-of-pocket costs" and "total drug costs," see Section 3.			(Of this amount, \$5,084.85 counts toward your "out-of-pocket costs." See definitions in Section 3.)

SECTION 2. Which “drug payment stage” are you in?

As shown below, your Part D prescription drug coverage has “drug payment stages.” How much you pay for a covered Part D prescription depends on which payment stage you are in when you fill it. During the calendar year, whether you move from one payment stage to the next depends on how much is spent for your drugs.

<p>STAGE 1 Yearly Deductible</p> <p>(Because there is no deductible for the plan, this payment stage does not apply to you.)</p>	<p>STAGE 2 Initial Coverage</p> <ul style="list-style-type: none"> You begin in this payment stage when you fill your first prescription of the year. During this stage, the plan pays its share of the cost of your drugs and you (or others on your behalf, including “Extra Help” from Medicare) pay your share of the cost. You generally stay in this stage until the amount of your “out-of-pocket costs” reaches \$5,100.00. Then you move to payment stage 4, Catastrophic Coverage. 	<p>STAGE 3 Coverage Gap</p> <p>(Because you are receiving “Extra Help” from Medicare, this payment stage does not apply to you.)</p>	<p>You are in this stage:</p> <p>STAGE 4 Catastrophic Coverage</p> <ul style="list-style-type: none"> During this payment stage, the plan pays for all your covered drugs. For each prescription, you pay nothing. 	<p>What happens next?</p> <p>When you are in this payment stage, Catastrophic Coverage, you generally stay in it for the rest of the year (through December 31, 2019).</p>
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SECTION 3. Your "out-of-pocket costs" and "total drug costs" (amounts and definitions)

We're including this section to help you keep track of your "out-of-pocket costs" and "total drug costs" because these costs determine which drug payment stage you are in. As explained in Section 2, the payment stage you are in determines how much you pay for your prescriptions.

<p>Your "out-of-pocket costs"</p> <p>\$5,100.00 month of January, 2019</p> <p>\$5,100.00 year-to-date (since January 1, 2019)</p>	<p>Your "total drug costs"</p> <p>\$26,155.12 month of January, 2019</p> <p>\$26,155.12 year-to-date (since January 1, 2019)</p>
<p>DEFINITION:</p> <p>"Out-of-pocket costs" includes:</p> <ul style="list-style-type: none"> What you pay when you fill or refill a prescription for a covered Part D drug. (This includes payments for your drugs, if any, that are made by family or friends.) Payments made for your drugs by any of the following programs or organizations: "Extra Help" from Medicare; Medicare's Coverage Gap Discount Program; Indian Health Service; AIDS drug assistance programs; most charities; and most State Pharmaceutical Assistance Programs (SPAPs). <p>It does <u>not</u> include:</p> <ul style="list-style-type: none"> Payments made for: a) plan premiums, b) drugs not covered by our plan, c) non-Part D drugs (such as drugs you receive during a hospital stay), d) drugs obtained at a non-network pharmacy that does not meet our out-of-network pharmacy access policy. Payments made for your drugs by any of the following programs or organizations: employer or union health plans; some government-funded programs, including TRICARE and the Veterans Administration; Workers' Compensation; and some other programs. 	<p>DEFINITION:</p> <p>"Total drug costs" is the total of all payments made for your covered Part D drugs. It includes:</p> <ul style="list-style-type: none"> What the plan pays. What you pay. What others (programs or organizations) pay for your drugs.

Learn more. Medicare has made the rules about which types of payments count and do not count toward "out-of-pocket costs" and "total drug costs". The definitions on this page give you only the main rules. For details, including more about "covered Part D drugs," see the Evidence of Coverage, or benefits booklet (for more about the Evidence of Coverage, see Section 6).

SECTION 4. Updates to the plan's Drug List that affect drugs you take

At this time, there are no new or upcoming changes to our Drug List that will affect the coverage or cost of drugs you take. (By "drugs you take," we mean any plan-covered drugs for which you filled prescriptions in the last 120 days or in 2019 as a member of our plan.)

SECTION 5. If you see mistakes on this summary or have questions, what should you do?

If you have questions, call us

If something is confusing or doesn't look right on this monthly prescription drug summary, please call us at Silver Script Choice (PDP) Customer Care (phone numbers are on the cover of this summary). You can also find answers to many questions on our website: www.silverscript.com.

What about possible fraud?

Most health care professionals and organizations that provide Medicare services are honest. Unfortunately, there may be some who are dishonest.

If this monthly summary shows drugs you're not taking, or anything else that looks suspicious to you, please contact us.

- Call us at Silver Script Choice (PDP) Customer Care (phone numbers are on the cover of this summary).
- Or, call Medicare at 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048. You can call these numbers for free, 24 hours a day, 7 days a week.

SECTION 6. Important things to know about your drug coverage and your rights

Your "Evidence of Coverage" and "LIS Rider" have the details about your drug coverage and costs

The Evidence of Coverage is our plan's benefits booklet. It explains your drug coverage and the rules you need to follow when you are

using your drug coverage. Your LIS Rider ("Evidence of Coverage Rider for People Who Get Extra Help Paying for Their Prescriptions") is a short separate document that tells what you pay for your prescriptions.

We have sent you a copy of the Evidence of Coverage and LIS Rider. If you need another copy of either of these, please call us (phone numbers are on the cover of this summary).

Remember, to get your drug coverage under our plan you must use pharmacies in our network, except in certain circumstances. Also, quantity limitations and restrictions may apply.

What if you have problems related to coverage or payments for your drugs?

Your Evidence of Coverage has step-by-step instructions that explain what to do if you have problems related to your drug coverage and costs. Here are the chapters to look for:

• Chapter 5. Asking the plan to pay its share of a bill you have received for covered services or drugs.

• Chapter 7. What to do if you have a problem or complaint (coverage decisions, appeals, complaints).

Here are things to keep in mind:

When we decide whether a drug is covered and how much you pay, it's called a "coverage decision." If you disagree with our coverage decision, you can appeal our decision (see Chapter 7 of the Evidence of Coverage).

Medicare has set the rules for how coverage decisions and appeals are handled. These are legal procedures and the deadlines are important. The process can take place if your doctor tells us that your health requires a quick decision.

Please ask for help if you need it. Here's how:

- You can call us at Silver Script Choice (PDP) Customer Care (phone numbers are on the cover of this monthly summary).
- You can call Medicare at 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048. You can call these numbers for free, 24 hours a day, 7 days a week.

You can call your State Health Insurance Assistance Program (SHIP). The name and phone numbers for this organization are in Chapter 2, Section 3 of your Evidence of Coverage.

Did you know there are programs to help people pay for their drugs?

- "Extra Help" from Medicare. You may be able to get "Extra Help" to pay for your prescription drug premiums and costs. This program is also called the "low-income subsidy" or LIS. People whose yearly income and resources are below certain limits can qualify for this help. To see if you qualify for getting "Extra Help," see Section 7 of your Medicare & You 2019 handbook or call 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048. You can call these numbers for free, 24 hours a day, 7 days a week. You can also call the Social Security Office at 1-800-772-1213 between 7 a.m. and 7 p.m., Monday through Friday. TTY users should call 1-800-325-0778. You can also call your State Medicaid Office.

- Help from your state's pharmaceutical assistance program. Many states have State Pharmaceutical Assistance Programs (SPAPs) that help some people pay for prescription drugs based on financial need, age, or medical condition. Each state has different rules. Check with your State Health Insurance Assistance Program (SHIP). The name and phone numbers for this organization are in Chapter 2, Section 3 of your Evidence of Coverage.

Silver Script® Insurance Company complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Silver Script Insurance Company does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

Silver Script Insurance Company:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Written information in other formats (large print, audio, accessible electronic formats, other formats)

- Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters

- Information written in other languages

If you need written information in other formats or free language services, please contact Customer Care. This number can be found on the back of your member ID card or on the letter that accompanied this card.

If you believe that Silver Script Insurance Company has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with: Silver Script Insurance Company, Grievance Department, P.O. Box 30016, Pittsburgh, PA 15222-0330. Fax: 1-866-217-3353.

You can file a grievance by mail, or by fax. If you need help filing a grievance, the Silver Script Grievance Department is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 1-800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

ENGLISH - ATTENTION: If you speak English, language assistance services, free of charge, are available to you. Call 1-866-235-5660 (TTY 711).

SPANISH - ATENCIÓN: Si usted habla español, tenemos servicios de **FRENCH - ATTENTION** : Si vous parlez français, des services asistencia lingüística disponibles para usted sin costo alguno. L'lame agra truits d'interprétation sont à votre disposition. Veuillez appeler le 1-866-235-5660 (TTY: 711).

CHINESE - 小貼士: 如果您說普通話, 歡迎使用免費語言協助服務。

請撥 1-866-235-5660 (TTY: 711)。

VIETNAMESE - CHÚ Ý: Nếu quý vị nói tiếng Việt, thì có sẵn các dịch vụ trợ giúp ngôn ngữ miễn phí dành cho quý vị. Hãy gọi số 1-866-235-5660 (TTY: 711).

KOREAN - 알림: 한국어를 하시는 경우 무료 통역 서비스가 준비되어 있습니다. 1-866-235-5660 (TTY: 711)로 연락주시기 바랍니다.

TAGALOG - PANSININ: Kung nagsasalita po kayo ng Tagalog, magagamit ninyo ang mga serbisyong tulong sa wika ng walang bayad. Tawagan po ang 1-866-235-5660 (TTY: 711).

RUSSIAN - ВНИМАНИЕ: Если вы говорите на русском языке, вам будут бесплатно предоставлены услуги переводчика. Звоните по телефону: 1-866-235-5660 (телефайп: 711).

ARABIC - ملاحظة: إذا كنت تتحدث العربية، تتوفر خدمات المساعدة اللغوية مجاناً من أجلك. اتصل بالرقم 1-866-235-5660 (الهاتف النصي: 711).

FRENCH CREOLE - ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 1-866-235-5660 (TTY: 711).

FRENCH - ATTENTION : Si vous parlez français, des services asistencia lingüística disponibles para usted sin costo alguno. L'lame agra truits d'interprétation sont à votre disposition. Veuillez appeler le 1-866-235-5660 (TTY: 711).

POLISH - UWAGA: Dla osób mówiących po polsku dostępna jest bezpłatna pomoc językowa. Zadzwoń pod numer 1-866-235-5660 (TTY: 711).

PORTUGUESE - ATENÇÃO: Se fala português, estão disponíveis serviços gratuitos de assistência linguística na sua língua. Telefone para 1-866-235-5660 (TTY: 711).

ITALIAN - ATTENZIONE: Se lei parla l'italiano, sono disponibili servizi gratuiti di assistenza linguistica nella sua lingua. Chiami 1-866-235-5660 (TTY: 711).

JAPANESE - お知らせ: 日本語での対応を望まれる方には、無料で通訳サービスをご利用になれます。電話番号 1-866-235-5660 (TTY: 711) までお問い合わせ下さい。

GERMAN - BITTE BEACHTEN: Wenn Sie Deutsch sprechen, stehen Ihnen unsere Dolmetscher unter der Nummer 1-866-235-5660 (TTY: 711) kostenlos zur Verfügung.

FARSI - توجه: چنانچه به زبان فارسی صحبت میکنید، خدمات کمک زبانی، به شما ارائه میشود. در اختیار شما قرار خواهد گرفت. یا شماره تماس بگیرید. (TTY: 711).

The formulary, pharmacy network, and/or provider network may change at any time. You will receive notice when necessary.

ATENCIÓN: Si usted habla español, tenemos servicios de asistencia lingüística disponibles para usted sin costo alguno. Llame al 1-866-235-5660 (TTY: 711).

EXHIBIT 56

EXHIBIT 57



P.O. Box 30013, Pittsburgh, PA 15222-0330

February 7, 2019

OK

**YOUR DRUG IS NOT ON OUR LIST OF COVERED DRUGS (FORMULARY)
OR IS SUBJECT TO CERTAIN LIMITS**

Dear [REDACTED]:

We want to tell you that SilverScript Choice (PDP) has provided you with a temporary supply of the following prescription: LEDIP-SOFOSB TAB 90-400MG.

This drug is either not included on our list of covered drugs (called our formulary), or it's included on the formulary but subject to certain limits, as described in more detail later in this letter. SilverScript Choice (PDP) is required to provide you with a temporary supply of this drug. If your prescription is written for fewer than 30 days, we'll allow multiple fills to provide up to a maximum 30-day supply of medication.

It's important to understand that this is a temporary supply of this drug. Well before you run out of this drug, you should speak to SilverScript Choice (PDP) and/or the prescriber about:

- changing the drug to another drug that is on our formulary; or
- requesting approval for the drug by demonstrating that you meet our criteria for coverage; or
- requesting an exception from our criteria for coverage.

When you request approval for coverage or an exception from coverage criteria, these are called coverage determinations. Don't assume that any coverage determination, including any exception, you have requested or appealed has been approved just because you receive more fills of a drug. If we approve coverage, then we'll send you another written notice.

If you need assistance in requesting a coverage determination, including an exception, or if you want more information about when we will cover a temporary supply of a drug, contact us at 1-866-235-5660. TTY users should call 711. Live representatives are available 24 hours a day, 7 days a week. You can ask us for a coverage determination at any time. **Instructions on how to change your current prescription, how to ask for a coverage determination (including an exception), and how to appeal a denial if you disagree with our coverage determination are discussed at the end of this letter.**

The following is a specific explanation of why your drug is not covered or is limited.

Name of Drug: LEDIP-SOFOSB TAB 90-400MG

Date Filled: 02/05/2019

Reason for Notification: This drug is not on our formulary. We will not continue to pay for this drug after you have received the maximum 30 days' temporary supply that we are required to cover unless you obtain a formulary exception from us.

CVS-002169

How do I change my prescription?

If your drug is not on our formulary, or is on our formulary but we have placed a limit on it, you can ask us what other drug used to treat your medical condition is on our formulary, ask us to approve coverage by showing that you meet our criteria, or ask us for an exception. We encourage you to ask your prescriber if this other drug that we cover is an option for you. You have the right to request an exception from us to cover your drug that was originally prescribed. If you ask for an exception, your prescriber will need to provide us with a statement explaining why a prior authorization, quantity limit, or other limit we have placed on your drug is not medically appropriate for you.

How do I request a coverage determination, including an exception?

You or your prescriber may contact us to request a coverage determination, including an exception. The toll-free phone number is 1-866-235-5660 (TTY users should call 711), or you may fax to 1-855-633-7673, or you may write to us at: SilverScript Insurance Company Prescription Drug Plans Coverage Decisions and Appeals Department, P.O. Box 52000, MC 109, Phoenix, AZ 85072-2000. We are available 24 hours a day, 7 days a week.

If you are requesting coverage of a drug that is not on our formulary or an exception to a coverage rule, your prescriber must provide a statement supporting your request. It may be helpful to bring this notice with you to the prescriber or send a copy to his or her office. If the exception request involves a drug that is not on our formulary, the prescriber's statement must indicate that the requested drug is medically necessary for treating your condition because all of the drugs on our formulary would be less effective than the requested drug or would have adverse effects for you. If the exception request involves a prior authorization or other coverage rule we have placed on a drug that is on our formulary, the prescriber's statement must indicate that the coverage rule wouldn't be appropriate for you given your condition or would have adverse effects for you.

We must notify you of our decision no later than 24 hours, if the request has been expedited, or no later than 72 hours, if the request is a standard request, from when we receive your request. For exceptions, the timeframe begins when we obtain your prescriber's statement. Your request will be expedited if we determine, or your prescriber tells us, that your life, health, or ability to regain maximum function may be seriously jeopardized by waiting for a standard decision.

What if my request for coverage is denied?

If your request for coverage is denied, you have the right to appeal by asking for a review of the prior decision, which is called a redetermination. You must request this appeal within 60 calendar days from the date of our written decision on your coverage determination request. We accept standard and expedited requests by telephone and in writing. Contact us at: SilverScript Insurance Company Prescription Drug Plans Coverage Decisions and Appeals Department, P.O. Box 52000, MC 109, Phoenix, AZ 85072-2000; phone: 1-866-235-5660; TTY: 711; fax: 1-855-633-7673; 24 hours a day, 7 days a week.

If you need assistance in requesting a coverage determination, including an exception, or if you want more information about when we will cover a temporary supply of a drug, contact us at 1-866-235-5660, 24 hours a day, 7 days a week. TTY users should call 711. Live representatives are available 24 hours a day, 7 days a week. You can ask us for a coverage determination at any time. You can also visit our website at www.silverscript.com.

Sincerely,

SilverScript Choice (PDP)

The formulary may change at any time. You will receive notice when necessary.

Beneficiaries must use network pharmacies to access their prescription drug benefit.

ATENCIÓN: Si usted habla español, tenemos servicios de asistencia lingüística disponibles para usted sin costo alguno. Llame al 1-866-235-5660 (TTY: 711).

SilverScript is a Prescription Drug Plan with a Medicare contract offered by SilverScript Insurance Company. Enrollment in SilverScript depends on contract renewal.

SilverScript® Insurance Company complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. SilverScript Insurance Company does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

SilverScript Insurance Company:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
 - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
 - Qualified interpreters
 - Information written in other languages

If you need written information in other formats or free language services, please contact Customer Care. This number can be found on the back of your member ID card or on the letter that accompanied this notice.

If you believe that SilverScript Insurance Company has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with: SilverScript Insurance Company, Grievance Department, P.O. Box 30016, Pittsburgh, PA 15222-0330. Fax: 1-866-217-3353.

You can file a grievance by mail, or by fax. If you need help filing a grievance, the SilverScript Grievance Department is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 1-800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

ENGLISH

ATTENTION: If you speak English, language assistance services, free of charge, are available to you. Call 1-866-235-5660 (TTY: 711).

SPANISH

ATENCIÓN: Si usted habla español, tenemos servicios de asistencia lingüística disponibles para usted sin costo alguno. Llame al 1-866-235-5660 (TTY: 711).

CHINESE

小贴士：如果您说普通话，欢迎使用免费语言协助服务。请拨1-866-235-5660 (TTY: 711)。

VIETNAMESE

CHÚ Ý: Nếu quý vị nói tiếng Việt, thì có sẵn các dịch vụ trợ giúp ngôn ngữ miễn phí dành cho quý vị. Hãy gọi số 1-866-235-5660 (TTY: 711).

KOREAN

알림: 한국어를 하시는 경우 무료 통역 서비스가 준비되어 있습니다. 1-866-235-5660 (TTY: 711)로 연락주시기 바랍니다.

TAGALOG

PANSININ: Kung nagsasalita po kayo ng Tagalog, magagamit ninyo ang mga serbisyong tulong sa wika ng walang bayad. Tawagan po ang 1-866-235-5660 (TTY: 711).

RUSSIAN

ВНИМАНИЕ: Если вы говорите на русском языке, вам будут бесплатно предоставлены услуги переводчика. Звоните по телефону: 1-866-235-5660 (телетайп: 711).

ARABIC

ملاحظة: إذا كنت تتحدث العربية، تتوفر خدمات المساعدة اللغوية مجاناً من أجلك. اتصل بالرقم 1-866-235-5660 (الهاتف النصي: 711).

FRENCH CREOLE

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 1-866-235-5660 (TTY: 711).

FRENCH

ATTENTION : Si vous parlez français, des services gratuits d'interprétation sont à votre disposition. Veuillez appeler le 1-866-235-5660 (TTY: 711).

POLISH

UWAGA: Dla osób mówiących po polsku dostępna jest bezpłatna pomoc językowa. Zadzwoń pod numer 1-866-235-5660 (TTY: 711).

PORTUGUESE

ATENÇÃO: Se fala português, estão disponíveis serviços gratuitos de assistência linguística na sua língua. Telefone para 1-866-235-5660 (TTY: 711).

ITALIAN

ATTENZIONE: Se lei parla italiano, sono disponibili servizi gratuiti di assistenza linguistica nella sua lingua. Chiami 1-866-235-5660 (TTY: 711).

JAPANESE

お知らせ: 日本語での対応を望まれる方には、無料で通訳サービスをご利用になれます。電話番号1-866-235-5660 (TTY: 711) までお問い合わせ下さい。

GERMAN

BITTE BEACHTEN: Wenn Sie Deutsch sprechen, stehen Ihnen unsere Dolmetscher unter der Nummer 1-866-235-5660 (TTY: 711) kostenlos zur Verfügung.

FARSI

توجه: چنانچه به زبان فارسی صحبت می‌کنید، خدمات کمک زبانی، به صورت رایگان، در اختیار شما قرار خواهد گرفت. با شماره 1-866-235-5660 (TTY: 711) تماس بگیرید.

EXHIBIT 58

Date	Time	Created By	Form of Contact	Activity	Tasks	Contact Duration (mm:ss)	Activity Notes
03-14-2019	11:17am	OUTLEY RAEGAL	INCORPUS PHONE CALL	CAPTURE ACTIVITY TEST CLAIM NDC. More activities		10:54	RECALL REPORTED BY [REDACTED] REASON CALLING 30465-4 REASON: 107666-2629202018618 HAWKING BECAUSE HE CANNOT AFFORD TO PICK UP H
03-14-2019	11:04am	WILSON VERONICA	INCORPUS PHONE CALL	CAPTURE ACTIVITY INTERNAL TRANSFER More activities		09:39	
03-14-2019	11:02am	HALL RUTH	INCORPUS PHONE CALL	INTERNAL TRANSFER VIEW ACCOUNT		01:14	call

EXHIBIT 59

Peoplesafe

Page 1 of 1

CAREMARK **PeopleSafe®** Close

Eligibility Maintenance **N** Participant Inquiry **N** Resolution Manager **N** Medicare D Inquiry **N** View Opportunities Tools: -- Select A Tool --

Client: **SILVERSCRIPT-INDIV-ENROLL** System: **RXCLAIM**

External ID: **[REDACTED]** Name: **[REDACTED]** Gndr: **M** Relationship: **MEMBER** Born: **[REDACTED] 1981** Effective: **01-01-2019** Expiration: **12-31-2039**

Main Screen Financial Details View Activity Prescription History Test Claims Plan Benefit Override Account Balance Explanation of Benefits Transaction History Communication History Caremark.com

Pharmacy Network Retail Transaction Plan Summary FSA/HSA/HRA History Coordination of Benefits Order Placement Adjustments Client Managed (G & A) View Triggers

Prescription for: **[REDACTED] MEMBER** Delivery System: **POINT OF SALE** Dispense As Written: **0 - NO DAW**
 Prescription Number: **[REDACTED]** [Go to Reimbursement...](#) Pharmacy NPI: **[REDACTED]** Drug Price Type: **AVERAGE WHOLESALE PRICE**
 Drug NDC: **61958180101** Pharmacy NCPDP: **[REDACTED]** Drug Price Source: **MEDISPAN**
 Drug Name: **HARVONI** Pharmacy Name: **[REDACTED]** Client Claim Price Type: **Alternate**

Participant Pay Participant Copy: 8.50 Initial Copy: 0.00 Gap Copy: 1819.59 Catastrophic Copy: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 8.50	Client Pay Usual and Customary: Cost Submitted: 37800.00 Cost Allowed: 32198.04 Other Payer Recognized: 0.00 Dispensing Fee: 0.50 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 32198.04	Pharmacy Pay: Usual and Customary: Cost Allowed: 32198.04 Other Payer Recognized: 0.00 Dispensing Fee: 0.50 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 32198.04
--	---	---

Health Reimbursement Account:
 Benefits: 0.00
 Member Access Fee: 0.00
 Amount Used: 0.00
 HRA Remaining Balance: 0.00

Med D Financials:
 LICIS Paid by Plan: 3330.03
 SPAP/Integrator Paid Amt: 0.00
 Reported Gap Discount: 0.00
 Deductible Gross Cost: 0.00
 Deductible Plan Pay: 0.00
 Initial Gross Cost: 0.00
 Initial Plan Pay: 0.00
 Gap Gross Cost: 1819.59
 Gap Plan Pay: 0.00
 Catastrophic Gross Cost: 30378.95
 Catastrophic Plan Pay: 28860.01

Miscellaneous
 Applied To Out of Pocket: 0.00
 Applied To TROOP: 0.00
 Applied To OOPM/MOOP: 0.00
 Paid by Other Insurance: 0.00
 Alternate Amount Paid: 0.00
 Previous Amount Paid: 0.00
 In Network Accumulation: 0.00
 Out of Network Accumulation: 0.00

View Settlement Codes View Comments Back

Pharmacy Reimbursement

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

Reversal

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

[View Reimbursements](#)

Recipient

Name:
 Alternate Name:
 Address:
 City:
 State:
 Zip:

[Go to top](#)

EXHIBIT 60

Harvoni & Epclusa Gx Rejected Claims (for the month of January 2019)

<u>Plan</u>	<u>Member State</u>	<u>Claim Fill Date</u>	<u>Product/Drug Label Name</u>
SILVERSCRIPT-INDIV-ENROLL	AL	1/9/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	AL	1/9/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	AL	1/9/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	AR	1/30/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	AZ	1/22/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	AZ	1/22/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	AZ	1/23/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	CA	1/22/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	CA	1/14/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	CA	1/10/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	CA	1/29/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	CA	1/29/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	CA	1/24/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	CA	1/24/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	CA	1/24/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	CA	1/24/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	CA	1/15/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	CO	1/17/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	CO	1/17/19	LEDIP-SOFOSB TAB 90-400MG

<u>Plan</u>	<u>Member State</u>	<u>Claim Fill Date</u>	<u>Product/Drug Label Name</u>
SILVERSCRIPT-INDIV-ENROLL	CO	1/14/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	CT	1/22/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	FL	1/28/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	FL	1/28/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	FL	1/15/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	FL	1/21/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	FL	1/22/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	FL	1/24/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	FL	1/28/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	FL	1/9/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	FL	1/30/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	GA	1/25/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	GA	1/31/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	GA	1/16/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	GA	1/28/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	IL	1/23/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	IL	1/23/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	IL	1/23/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	IL	1/23/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	IL	1/23/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	IN	1/22/19	SOFOS/VELPAT TAB 400-100

<u>Plan</u>	<u>Member State</u>	<u>Claim Fill Date</u>	<u>Product/Drug Label Name</u>
SILVERSCRIPT-INDIV-ENROLL	IN	1/18/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	IN	1/18/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	IN	1/28/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	KS	1/28/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	KY	1/31/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	MA	1/11/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	MA	1/11/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	MA	1/10/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	MA	1/9/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	MA	1/17/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	MD	1/11/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	ME	1/30/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	MI	1/11/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	MI	1/30/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	MI	1/30/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	MI	1/18/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	MI	1/22/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	MI	1/24/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	MI	1/24/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	MI	1/17/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	MO	1/28/19	SOFOS/VELPAT TAB 400-100

<u>Plan</u>	<u>Member State</u>	<u>Claim Fill Date</u>	<u>Product/Drug Label Name</u>
SILVERSCRIPT-INDIV-ENROLL	MO	1/23/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	MO	1/23/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	MO	1/23/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	MO	1/30/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	MO	1/30/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	MS	1/28/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	MS	1/29/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	MS	1/31/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	NC	1/22/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	NC	1/30/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	NY	1/10/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	NY	1/21/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	NY	1/21/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	NY	1/28/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	OR	1/7/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	PA	1/31/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	PA	1/9/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	RI	1/3/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	SC	1/22/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	TN	1/23/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	TN	1/30/19	SOFOS/VELPAT TAB 400-100

<u>Plan</u>	<u>Member State</u>	<u>Claim Fill Date</u>	<u>Product/Drug Label Name</u>
SILVERSCRIPT-INDIV-ENROLL	TN	1/21/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	TN	1/22/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	TN	1/7/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	TX	12/21/18	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	TX	1/23/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	VA	1/25/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	VT	1/24/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	VT	1/24/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	WA	1/9/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	WI	12/18/18	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	WI	12/18/18	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	WI	12/18/18	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	WI	1/2/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	WI	1/21/19	LEDIP-SOFOSB TAB 90-400MG
SILVERSCRIPT-INDIV-ENROLL	WV	1/30/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	WV	1/31/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	WV	1/28/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	WV	1/30/19	SOFOS/VELPAT TAB 400-100
SILVERSCRIPT-INDIV-ENROLL	WV	1/31/19	SOFOS/VELPAT TAB 400-100

EXHIBIT 61

MED D - VENTOLIN® HFA Generic Not Available for SilverScript Choice, Plus, and Allure (PDP) Plans Until Further Notice

[Overview](#)

[Background](#)

[What does this mean for the beneficiary?](#)

[Effects of this Strategy on Beneficiaries](#)

[FAQs](#)

[Log Activity](#)

[Resolution Time](#)

[Related Documents](#)

[Parent SOP](#)

[Abbreviations / Definitions](#)

Overview

VENTOLIN® HFA is a branded prescription drug commonly used for the treatment of asthma. This prescription drug was recently launched in its generic form, albuterol sulfate inhalation aerosol. The generic form of VENTOLIN HFA is not available on SilverScript Choice, Plus, or Allure (PDP) plans until further notice.

VENTOLIN® HFA will be MAINTAINED on the Preferred Brand Tier (Tier 3) in 2019 on the formularies for SilverScript Choice, Plus, and Allure beneficiaries. The generic, albuterol sulfate inhalation aerosol, will **NOT** be added to the formularies.

This applies only to SilverScript Choice, Plus, and Allure beneficiaries in 2019.

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Background

Generic prescription drugs are typically the lowest-cost option when compared to branded prescription drugs. SilverScript **promotes the use of generic prescription drugs** to help plan beneficiaries save money.

- During the initial launch phase for the generic, there will be few manufacturers marketing the generic and the cost of the generic is expected to be relatively high.
- To help keep out-of-pocket costs low, SilverScript is retaining brand VENTOLIN® HFA on its formulary on Preferred Brand Tier (Tier 3). VENTOLIN is eligible for a manufacturer discount in the coverage gap.
- SilverScript will continue to keep the brand version of VENTOLIN HFA on the formulary and will **NOT** be adding the generic version until further notice.

Note: SilverScript Employer PDP Plans are being handled differently.

- **SilverScript Choice, Plus, and Allure Plans**

The generic version of VENTOLIN HFA (albuterol sulfate inhalation aerosol) will **NOT** be added to the SilverScript formularies for SilverScript Choice, Plus, and Allure plans in 2019.

- **SilverScript Employer PDP Plans**

Employer PDP Plans may add the generic (albuterol sulfate inhalation aerosol) to their formulary for 2019. Some plans will continue cover the brand in 2019.

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What does this mean for the beneficiary?

Retaining brand VENTOLIN HFA on Preferred Brand Tier (Tier 3) can help keep out-of-pocket costs low for SilverScript beneficiaries.

Note: The generic equivalent albuterol sulfate inhalation aerosol is **not** be on the formulary until further notice.

- Beneficiaries have the option to request an exception if they wish to obtain albuterol sulfate inhalation aerosol.
 - However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.
- Brand VENTOLIN HFA is available at the Preferred Brand Tier (Tier 3) copay/coinsurance, so if the request for the generic is granted, the beneficiary would pay the amount associated with the plan's exception tier. This may be a different cost than the brand.

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Effects of this Strategy on Beneficiaries

- Beneficiaries will continue to receive the brand VENTOLIN HFA at the Preferred Brand Tier (Tier 3) cost share.
- The CCR may receive calls from MED D beneficiaries who are confused about the lack of generic version availability of the prescription drug. Refer to the [FAQs](#) section of this document for appropriate responses.

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FAQs

The frequently asked questions below will assist the CCR when addressing incoming calls regarding VENTOLIN HFA.


Note: These specifics apply to non-LIS beneficiaries. See specific Q&A at end of this FAQ section for LIS-specific information.

Question	Answer	
Will VENTOLIN HFA cost more than albuterol sulfate inhalation aerosol in any stage of the Medicare D benefit for non-LIS beneficiaries?	SAY: <ul style="list-style-type: none">This will vary based on your Plan and which Medicare Part D coverage stage you currently are in (e.g., Deductible, Initial Coverage Limits, Coverage Gap or Catastrophic). CCR Process Note: The CCR will review the following grid for information on the anticipated costs of VENTOLIN HFA vs. albuterol sulfate inhalation aerosol during the albuterol sulfate inhalation aerosol initial launch period:	
	Deductible Stage for non-LIS beneficiaries:	SilverScript Choice , Plus, and Allure beneficiaries: <ul style="list-style-type: none">In 2019, no deductible except for Choice Plan beneficiaries who will have a \$100 annual deductible for drugs in Tiers 3 to 5 for beneficiaries residing in Colorado, Georgia, or Texas; Choice beneficiaries residing in Arizona and South Carolina will have a \$415 annual deductible for drugs in Tiers 3 to 5, or Alaska will have a \$415 deductible for all drugs. SilverScript Plus and Allure Plans do not have a deductible. Move to response below in Initial Coverage Limits Stage.
	Initial Coverage Limits (ICL) Stage for non-LIS beneficiaries:	SAY: <ul style="list-style-type: none">Maybe.You will continue to pay your current Preferred Brand Tier (Tier 3) cost share during the

		<ul style="list-style-type: none"> Initial Coverage Limits stage for brand VENTOLIN HFA. Mr. /Mrs. <Beneficiary>, your cost share for brand VENTOLIN HFA will be <\$X.XX>. <p>Move to response below in Coverage Gap Stage.</p>
	Coverage Gap Stage for non-LIS beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> No. The Coverage Gap Stage (also called the donut hole) is where you will receive significant savings on brand VENTOLIN HFA. The brand name is less expensive than the generic version because of the manufacturer discount on brand name prescription drugs. In 2019, your cost share in the Coverage Gap Stage is 25% of the price of brand VENTOLIN HFA. If the generic were included at this time on the formulary, your cost share would be 37%. <p>Move to response below in Catastrophic Coverage Stage.</p>
	Catastrophic Stage for non-LIS beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> Yes. During this stage of the benefit, it is expected that - because of the price of the brand and generic versions - you will pay 5% of the

	<ul style="list-style-type: none"> • allowed cost.
Why is the brand-name VENTOLIN HFA on the formulary when there is now a generic available?	<p>SAY:</p> <ul style="list-style-type: none"> • In this case, the price of the generic version of VENTOLIN HFA will likely be similar to the price of the brand version for a minimum of six months, and perhaps longer. • There are few manufacturers of the generic version of VENTOLIN HFA to drive the price down. • Until there are competitors and the price of the generic version goes down, your plan will continue to cover brand-name VENTOLIN HFA at the Preferred Brand Tier (Tier 3) cost share in 2019.
Why can't I get the generic? Aren't generics less expensive?	<p>SAY:</p> <ul style="list-style-type: none"> • When a generic version is first available, it is typically similar in price to the brand version. • At this time the generic version, called albuterol sulfate inhalation aerosol, is not on the formulary. <ul style="list-style-type: none"> ○ You do have the option to request a formulary exception. ○ However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.
Will my other copays for other prescription drugs be lowered?	<p>SAY:</p> <ul style="list-style-type: none"> • No. • You will continue to pay the copay/coinsurance for other brand name and generic prescription drugs at the current benefit copay.
Could there be other brand prescription drugs that	<p>SAY:</p> <ul style="list-style-type: none"> •

this applies to?	<ul style="list-style-type: none"> • In most cases the generic version of a prescription drug is less expensive than the brand name version and is covered at the lower generic copay. • The exception typically applies during the first few years the generic version of a prescription drug is launched.
How long will VENTOLIN HFA remain on the formulary on the Preferred Brand Tier (Tier 3)?	<p>SAY:</p> <ul style="list-style-type: none"> • We anticipate that VENTOLIN HFA will remain on the formulary on the Preferred Brand Tier (Tier 3) in 2019 until the price of the generic form of VENTOLIN HFA drops. • We anticipate it will be a minimum of six months, however that is based on market conditions not within our control and could change.
What should I do if brand VENTOLIN HFA is removed from the formulary during the plan year?	<p>SAY:</p> <ul style="list-style-type: none"> • We will provide you with prior notification if brand VENTOLIN HFA removed from the formulary during the Plan year. • The type of notification depends on whether you are using the prescription drug and whether the change happens during the plan year or at the beginning of the next plan year. <ul style="list-style-type: none"> ○ If we make this change during the plan year, and you are using VENTOLIN HFA, you will receive written notification of the change in your Explanation of Benefits (EOB). ○ If we make this change at the beginning of the next plan year, the change will be noted in the formulary included as part of your Annual Notice of Change (ANOC) packet.

	<ul style="list-style-type: none"> ○ You should review your plan's formulary carefully. • If brand VENTOLIN HFA is removed from the formulary and you want to continue using brand VENTOLIN HFA, you will have the option to request a formulary exception. • However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level. 	
May I, as the beneficiary, request a coverage determination for the generic product?	<p>SAY:</p> <ul style="list-style-type: none"> • Yes, you as the beneficiary may request a coverage determination for albuterol sulfate inhalation aerosol. <ul style="list-style-type: none"> ○ However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level. <p> Refer to the Med D Care - Coverage Determination/Appeal (New or Status Update) document.</p>	
Will albuterol sulfate inhalation aerosol be added to the formulary during the 2019 plan year?	<p>SAY:</p> <p>The addition of the generic to the formulary will be re-evaluated during the year.</p>	
Will VENTOLIN HFA cost more than albuterol sulfate inhalation aerosol in any stage of the Medicare Part D benefit for LIS beneficiaries?	<p>CCR Process Note: The CCR will review the following information for LIS beneficiaries on the anticipated costs of VENTOLIN HFA vs. albuterol sulfate inhalation aerosol during the albuterol sulfate inhalation aerosol initial launch period:</p>	
	For LIS 1 & 2 Beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> • Maybe. • In the Catastrophic Coverage Stage of the

		<ul style="list-style-type: none"> • benefit, you will continue to receive VENTOLIN HFA at no cost. • If you have not yet reached the Catastrophic Coverage Stage, you might have to pay your brand name copayment for VENTOLIN HFA until you reach the Catastrophic Coverage Stage.
	FOR LIS 3 Beneficiaries:	SAY: <ul style="list-style-type: none"> • No.
	FOR LIS 4 Beneficiaries:	SAY: <ul style="list-style-type: none"> • Maybe. • If you are in the Initial Coverage Limits Stage (ICL) or the Post-Initial Coverage Limits Stage of the benefit you will continue to pay your current coinsurance for VENTOLIN HFA. • If you are in the Catastrophic Coverage Stage, you will continue to pay the LIS brand name copayment for VENTOLIN HFA.

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Log Activity

1003 – Plan Design Education

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Resolution Time

Information = immediate

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Related Documents

Grievance Standard Verbiage (for use in Discussion with Beneficiary) section in [MED D Care - Grievances in PeopleSafe and MedHOK](#)

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Parent SOP

CALL-0048: [Medicare Part D Customer Care Call Center Requirements- CVS Caremark Part D Services, L.L.C.](#)

[Top of the Document](#)

Abbreviations / Definitions

[Mail Service Customer Care Abbreviations and Definitions](#)

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EXHIBIT 62

Peoplesafe

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CAREMARK **PeopleSafe®** Close

Eligibility Maintenance Participant Inquiry Resolution Manager Medicare Inquiry View Opportunities Tools: -- Select A Tool --

Client: SILVERSCRIPT-INDIV-ENROLL System: RXCLAIM

External ID: XXXXXXXXXX Name: XXXXXXXXXX Gndr: F Relationship: MEMBER Born: XXXXXX 945 Effective: 01-01-2019 Expiration: 12-31-2039

[Main Screen](#) [Financial Details](#) [View Activity](#) [Prescription History](#) [Test Claims](#) [Plan Benefit Overview](#) [Account Balance](#) [Explanation of Benefits](#) [Transaction History](#) [Communication History](#) [Carmark.com](#)

[Pharmacy Network](#) [Retail Transaction](#) [Plan Summary](#) [FSA/HSA/HRA History](#) [Coordination of Benefits](#) [Order Placement](#) [Adjustments](#) [Client Managed G & A](#) [View Triggers](#)

Prescription for: MEMBER Delivery System: POINT OF SALE
 Prescription Number: XXXXXXXXXX [Go to Reimbursement...](#) Pharmacy NPI: XXXXXXXXXX Dispense As Written: 0 - NO DAW
 Drug NDC: 66993001968 Pharmacy NCPDP: XXXXXXXXXX Drug Price Type: AVERAGE WHOLESALE PRICE
 Drug Name: [ALBUTEROL SULFATE HFA](#) Pharmacy Name: [KROGER PHARMACY](#) Drug Price Source: MEDISPAN
 Client Claim Price Type: Pharmacy Claim Price Type:

Participant Pay Participant Copay: 18.89 Initial Copay: 18.89 Gap Copay: 0.00 Catastrophic Copay: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 18.89	Client Pay Usual and Customary: Cost Submitted: 62.44 Cost Allowed: 46.83 Other Payer Recognized: 0.00 Dispensing Fee: 0.40 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 ===== Total Client Cost: 28.34	Pharmacy Pay: Usual and Customary: Cost Allowed: 46.83 Other Payer Recognized: 0.00 Dispensing Fee: 0.40 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 ===== Total Pharmacy Reimbursement: 28.34
--	---	--

Health Reimbursement Account:
 Benefits: 0.00
 Member Access Fee: 0.00
 Amount Used: 0.00
 HRA Remaining Balance: 0.00

Med D Financials:
 LICs Paid by Plan: 0.00
 SPAP/Integrator Paid Amt: 0.00
 Reported Gap Discount: 0.00
 Deductible Gross Cost: 0.00
 Deductible Plan Pay: 0.00
 Initial Gross Cost: 47.23
 Initial Plan Pay: 28.34
 Gap Gross Cost: 0.00
 Gap Plan Pay: 0.00
 Catastrophic Gross Cost: 0.00
 Catastrophic Plan Pay: 0.00

Miscellaneous
 Applied To Out of Pocket: 0.00
 Applied To TROOP: 0.00
 Applied To OOPM/MOOP: 0.00
 Paid by Other Insurance: 0.00
 Alternate Amount Paid: 0.00
 Previous Amount Paid: 0.00
 In Network Accumulation: 0.00
 Out of Network Accumulation: 0.00

[View Settlement Codes](#) [View Comments](#) [Back](#)

Pharmacy Reimbursement

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

Reversal

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

[View Reimbursements](#)

Recipient

Name:
 Alternate Name:
 Address:
 City:
 State:
 Zip:

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EXHIBIT 63



P.O. Box 30013, Pittsburgh, PA 15222-0330

February 12, 2019

**YOUR DRUG IS NOT ON OUR LIST OF COVERED DRUGS (FORMULARY)
OR IS SUBJECT TO CERTAIN LIMITS**

Dear [REDACTED]

We want to tell you that SilverScript Allure (PDP) has provided you with a temporary supply of the following prescription: ALBUTEROL AER HFA.

This drug is either not included on our list of covered drugs (called our formulary), or it's included on the formulary but subject to certain limits, as described in more detail later in this letter. SilverScript Allure (PDP) is required to provide you with a temporary supply of this drug. If your prescription is written for fewer than 30 days, we'll allow multiple fills to provide up to a maximum 30-day supply of medication.

It's important to understand that this is a temporary supply of this drug. Well before you run out of this drug, you should speak to SilverScript Allure (PDP) and/or the prescriber about:

- changing the drug to another drug that is on our formulary; or
- requesting approval for the drug by demonstrating that you meet our criteria for coverage; or
- requesting an exception from our criteria for coverage.

When you request approval for coverage or an exception from coverage criteria, these are called coverage determinations. Don't assume that any coverage determination, including any exception, you have requested or appealed has been approved just because you receive more fills of a drug. If we approve coverage, then we'll send you another written notice.

If you need assistance in requesting a coverage determination, including an exception, or if you want more information about when we will cover a temporary supply of a drug, contact us at 1-866-235-5660. TTY users should call 711. Live representatives are available 24 hours a day, 7 days a week. You can ask us for a coverage determination at any time. **Instructions on how to change your current prescription, how to ask for a coverage determination (including an exception), and how to appeal a denial if you disagree with our coverage determination are discussed at the end of this letter.**

The following is a specific explanation of why your drug is not covered or is limited.

Name of Drug: ALBUTEROL AER HFA

Date Filled: 02/09/2019

Reason for Notification: This drug is not on our formulary. We will not continue to pay for this drug after you have received the maximum 30 days' temporary supply that we are required to cover unless you obtain a formulary exception from us.

How do I change my prescription?

If your drug is not on our formulary, or is on our formulary but we have placed a limit on it, you can ask us what other drug used to treat your medical condition is on our formulary, ask us to approve coverage by showing that you meet our criteria, or ask us for an exception. We encourage you to ask your prescriber if this other drug that we cover is an option for you. You have the right to request an exception from us to cover your drug that was originally prescribed. If you ask for an exception, your prescriber will need to provide us with a statement explaining why a prior authorization, quantity limit, or other limit we have placed on your drug is not medically appropriate for you.

How do I request a coverage determination, including an exception?

You or your prescriber may contact us to request a coverage determination, including an exception. The toll-free phone number is 1-866-235-5660 (TTY users should call 711), or you may fax to 1-855-633-7673, or you may write to us at: SilverScript Insurance Company Prescription Drug Plans Coverage Decisions and Appeals Department, P.O. Box 52000, MC 109, Phoenix, AZ 85072-2000. We are available 24 hours a day, 7 days a week.

If you are requesting coverage of a drug that is not on our formulary or an exception to a coverage rule, your prescriber must provide a statement supporting your request. It may be helpful to bring this notice with you to the prescriber or send a copy to his or her office. If the exception request involves a drug that is not on our formulary, the prescriber's statement must indicate that the requested drug is medically necessary for treating your condition because all of the drugs on our formulary would be less effective than the requested drug or would have adverse effects for you. If the exception request involves a prior authorization or other coverage rule we have placed on a drug that is on our formulary, the prescriber's statement must indicate that the coverage rule wouldn't be appropriate for you given your condition or would have adverse effects for you.

We must notify you of our decision no later than 24 hours, if the request has been expedited, or no later than 72 hours, if the request is a standard request, from when we receive your request. For exceptions, the timeframe begins when we obtain your prescriber's statement. Your request will be expedited if we determine, or your prescriber tells us, that your life, health, or ability to regain maximum function may be seriously jeopardized by waiting for a standard decision.

What if my request for coverage is denied?

If your request for coverage is denied, you have the right to appeal by asking for a review of the prior decision, which is called a redetermination. You must request this appeal within 60 calendar days from the date of our written decision on your coverage determination request. We accept standard and expedited requests by telephone and in writing. Contact us at: SilverScript Insurance Company Prescription Drug Plans Coverage Decisions and Appeals Department, P.O. Box 52000, MC 109, Phoenix, AZ 85072-2000; phone: 1-866-235-5660; TTY: 711; fax: 1-855-633-7673; 24 hours a day, 7 days a week.

If you need assistance in requesting a coverage determination, including an exception, or if you want more information about when we will cover a temporary supply of a drug, contact us at 1-866-235-5660, 24 hours a day, 7 days a week. TTY users should call 711. Live representatives are available 24 hours a day, 7 days a week. You can ask us for a coverage determination at any time. You can also visit our website at www.silverscript.com.

Sincerely,

SilverScript Allure (PDP)

The formulary may change at any time. You will receive notice when necessary.

Beneficiaries must use network pharmacies to access their prescription drug benefit.

ATENCIÓN: Si usted habla español, tenemos servicios de asistencia lingüística disponibles para usted sin costo alguno. Llame al 1-866-235-5660 (TTY: 711).

SilverScript is a Prescription Drug Plan with a Medicare contract offered by SilverScript Insurance Company. Enrollment in SilverScript depends on contract renewal.

SilverScript® Insurance Company complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. SilverScript Insurance Company does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

SilverScript Insurance Company:

- § Provides free aids and services to people with disabilities to communicate effectively with us, such as:
 - Written information in other formats (large print, audio, accessible electronic formats, other formats)

- § Provides free language services to people whose primary language is not English, such as:
 - Qualified interpreters
 - Information written in other languages

If you need written information in other formats or free language services, please contact Customer Care. This number can be found on the back of your member ID card or on the letter that accompanied this notice.

If you believe that SilverScript Insurance Company has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with: SilverScript Insurance Company, Grievance Department, P.O. Box 30016, Pittsburgh, PA 15222-0330. Fax: 1-866-217-3353.

You can file a grievance by mail, or by fax. If you need help filing a grievance, the SilverScript Grievance Department is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 1-800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

[REDACTED]

[REDACTED]

[REDACTED]

ENGLISH

ATTENTION: If you speak English, language assistance services, free of charge, are available to you. Call 1-866-235-5660 (TTY*711).

SPANISH

ATENCIÓN: Si usted habla español, tenemos servicios de asistencia lingüística disponibles para usted sin costo alguno. Llame al 1-866-235-5660 (TTY: 711).

CHINESE

* * * * *
* * * * * 1-866-235-5660 (TTY:
711)*

VIETNAMESE

CHÚ Ý: Nếu quý vị nói tiếng Việt, thì có sẵn các dịch vụ trợ giúp ngôn ngữ miễn phí dành cho quý vị. Hãy gọi số 1-866-235-5660 (TTY: 711).

KOREAN

* * * * *
* * * * *
1-866-235-5660 (TTY: 711)* * * * *
* * * * *

TAGALOG

PANSININ: Kung nagsasalita po kayo ng Tagalog, magagamit ninyo ang mga serbisyong tulong sa wika ng walang bayad. Tawagan po ang *****235-5660 (TTY: 711).

RUSSIAN

ВНИМАНИЕ: Если вы говорите на русском языке, вам будут бесплатно предоставлены услуги переводчика. Звоните по телефону: 1-866-235-5660 (телетайп: 711).

ARABIC

ملاحظة: إذا كنت تتحدث العربية، تتوفر خدمات المساعدة اللغوية مجاناً. امن أهلك. اتصل بالرقم 1-866-235-5660 (الهاتف النصي: 711).

FRENCH CREOLE

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 1-866-235-5660 (TTY: 711).

FRENCH

ATTENTION : Si vous parlez français, des services gratuits d'interprétation sont à votre disposition. Veuillez appeler le 1-866-235-5660 (TTY: 711).

POLISH

UWAGA: Dla osób mówiących po polsku dostępna jest bezpłatna pomoc językowa. Zadzwoń pod numer 1-866-235-5660 (TTY: 711).

PORTUGUESE

ATENÇÃO: Se fala português, estão disponíveis serviços gratuitos de assistência linguística na sua língua. Telefone para 1-866-235-5660 (TTY: 711).

ITALIAN

ATTENZIONE: Se lei parla italiano, sono disponibili servizi gratuiti di assistenza linguistica nella sua lingua. Chiami 1-866-235-5660 (TTY: 711).

JAPANESE

* * * * *
* * * * *
* * * * * 1-866-235-5660 (TTY: 711) * *
* * * * *

GERMAN

BITTE BEACHTEN: Wenn Sie Deutsch sprechen, stehen Ihnen unsere Dolmetscher unter der Nummer 1-866-235-5660 (TTY: 711) kostenlos zur Verfügung.

FARSI

توجه: چنانچه به زبان فارسی صحبت می کنید، خدمات کمک زبانی، به صورت رایگان در اختیار شما قرار خواهد گرفت. با شماره 1-866-235-5660 (TTY: 711) تماس بگیرید.

EXHIBIT 64

Peoplesafe

Page 1 of 1

CAREMARK **PeopleSafe®** Close

Eligibility Maintenance Participant Inquiry Resolution Manager Medicare Inquiry View Opportunities Tools: -- Select A Tool --

Client: **SILVERSCRIPT-INDIV-ENROLL** System: **RXCLAIM**

External ID: **[REDACTED]** Name: **[REDACTED]** Gender: **F** Relationship: **MEMBER** Born: **[REDACTED] 945** Effective: **01-01-2019** Expiration: **12-31-2039**

Navigation: [Main Screen](#) [Financial Details](#) [View Activity](#) [Prescription History](#) [Test Claims](#) [Plan Benefit Overview](#) [Account Balance](#) [Explanation of Benefits](#) [Transaction History](#) [Communication History](#) [Caremark.com](#)

Pharmacy Network [Retail Transaction](#) [Plan Summary](#) [FSA/HSA/HRA History](#) [Coordination of Benefits](#) [Order Placement](#) [Adjustments](#) [Client Managed G & A](#) [View Triggers](#)

Prescription for: **[REDACTED] MEMBER** Delivery System: **POINT OF SALE** Dispense As Written: **2 - PATIENT DAW**

Prescription Number: **[REDACTED]** [Go to Reimbursement...](#) Pharmacy NPI: **[REDACTED]** Drug Price Type: **AVERAGE WHOLESALE PRICE**

Drug NDC: **173068220** Pharmacy NCPDP: **[REDACTED]** Drug Price Source: **MEDISPAN**

Drug Name: **VENTOLIN HFA** Pharmacy Name: **KROGER PHARMACY** Pharmacy Claim Price Type:

Participant Pay Participant Copay: 6.20 Initial Copay: 6.20 Gap Copay: 0.00 Catastrophic Copay: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 6.20	Client Pay Usual and Customary: 66.43 Cost Submitted: 66.43 Cost Allowed: 30.61 Other Payer Recognized: 0.00 Dispensing Fee: 0.40 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 24.81	Pharmacy Pay: Usual and Customary: 55.80 Cost Allowed: 55.80 Other Payer Recognized: 0.00 Dispensing Fee: 0.40 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 50.00
---	--	---

Health Reimbursement Account:
 Benefits: 0.00
 Member Access Fee: 0.00
 Amount Used: 0.00
 HRA Remaining Balance: 0.00

Med D Financials:
 LICs Paid by Plan: 0.00
 SPAP/Integrator Paid Amt: 0.00
 Reported Gap Discount: 0.00
 Deductible Gross Cost: 0.00
 Deductible Plan Pay: 0.00
 Initial Gross Cost: 31.01
 Initial Plan Pay: 24.81
 Gap Gross Cost: 0.00
 Gap Plan Pay: 0.00
 Catastrophic Gross Cost: 0.00
 Catastrophic Plan Pay: 0.00

Miscellaneous
 Applied To Out of Pocket: 0.00
 Applied To TROOP: 0.00
 Applied To OOPM/MOOP: 0.00
 Paid by Other Insurance: 0.00
 Alternate Amount Paid: 0.00
 Previous Amount Paid: 0.00
 In Network Accumulation: 0.00
 Out of Network Accumulation: 0.00

[View Settlement Codes](#) [View Comments](#) [Back](#)

Pharmacy Reimbursement

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

Reversal

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

[View Reimbursements](#)

Recipient

Name:
 Alternate Name:
 Address:
 City:
 State:
 Zip:

[Go to top](#)

EXHIBIT 65

Generic Ventolin HFA Transition Fill Claims (2019.02.07 to 2019.02.13)

<u>STATE</u>	<u>DATE FILL</u>	<u>NDC</u>	<u>DRUG</u>
LA	20190207	66993001968	ALBUTEROL AER HFA
MS	20190207	66993001968	ALBUTEROL AER HFA
ID	20190207	66993001968	ALBUTEROL AER HFA
AR	20190207	66993001968	ALBUTEROL AER HFA
FL	20190207	66993001968	ALBUTEROL AER HFA
NY	20190207	66993001968	ALBUTEROL AER HFA
OK	20190207	66993001968	ALBUTEROL AER HFA
WA	20190207	66993001968	ALBUTEROL AER HFA
MO	20190207	66993001968	ALBUTEROL AER HFA
IL	20190207	66993001968	ALBUTEROL AER HFA
OK	20190207	66993001968	ALBUTEROL AER HFA
CA	20190207	66993001968	ALBUTEROL AER HFA
CA	20190207	66993001968	ALBUTEROL AER HFA
NH	20190207	66993001968	ALBUTEROL AER HFA
NC	20190207	66993001968	ALBUTEROL AER HFA
IL	20190207	66993001968	ALBUTEROL AER HFA
AR	20190207	66993001968	ALBUTEROL AER HFA
CA	20190207	66993001968	ALBUTEROL AER HFA
AR	20190207	66993001968	ALBUTEROL AER HFA
MO	20190207	66993001968	ALBUTEROL AER HFA
CO	20190207	66993001968	ALBUTEROL AER HFA
FL	20190207	66993001968	ALBUTEROL AER HFA
AR	20190207	66993001968	ALBUTEROL AER HFA
NJ	20190207	66993001968	ALBUTEROL AER HFA
TX	20190207	66993001968	ALBUTEROL AER HFA
NM	20190207	66993001968	ALBUTEROL AER HFA
OH	20190207	66993001968	ALBUTEROL AER HFA
FL	20190207	66993001968	ALBUTEROL AER HFA
FL	20190207	66993001968	ALBUTEROL AER HFA
SC	20190207	66993001968	ALBUTEROL AER HFA
OH	20190207	66993001968	ALBUTEROL AER HFA
IL	20190207	66993001968	ALBUTEROL AER HFA
NY	20190207	66993001968	ALBUTEROL AER HFA
MD	20190207	66993001968	ALBUTEROL AER HFA
PA	20190207	66993001968	ALBUTEROL AER HFA
NY	20190207	66993001968	ALBUTEROL AER HFA

STATE	DATE FILL	NDC	DRUG
OH	20190207	66993001968	ALBUTEROL AER HFA
OR	20190207	66993001968	ALBUTEROL AER HFA
FL	20190207	66993001968	ALBUTEROL AER HFA
TX	20190207	66993001968	ALBUTEROL AER HFA
KS	20190207	66993001968	ALBUTEROL AER HFA
MA	20190207	66993001968	ALBUTEROL AER HFA
OH	20190207	66993001968	ALBUTEROL AER HFA
WV	20190207	66993001968	ALBUTEROL AER HFA
FL	20190207	66993001968	ALBUTEROL AER HFA
PA	20190207	66993001968	ALBUTEROL AER HFA
AL	20190207	66993001968	ALBUTEROL AER HFA
CA	20190207	66993001968	ALBUTEROL AER HFA
CA	20190207	66993001968	ALBUTEROL AER HFA
CO	20190207	66993001968	ALBUTEROL AER HFA
CA	20190207	66993001968	ALBUTEROL AER HFA
SC	20190207	66993001968	ALBUTEROL AER HFA
MS	20190207	66993001968	ALBUTEROL AER HFA
MN	20190207	66993001968	ALBUTEROL AER HFA
NY	20190207	66993001968	ALBUTEROL AER HFA
KS	20190207	66993001968	ALBUTEROL AER HFA
MD	20190207	66993001968	ALBUTEROL AER HFA
OH	20190207	66993001968	ALBUTEROL AER HFA
MI	20190207	66993001968	ALBUTEROL AER HFA
FL	20190207	66993001968	ALBUTEROL AER HFA
IL	20190207	66993001968	ALBUTEROL AER HFA
WI	20190207	66993001968	ALBUTEROL AER HFA
KY	20190207	66993001968	ALBUTEROL AER HFA
NE	20190207	66993001968	ALBUTEROL AER HFA
OK	20190207	66993001968	ALBUTEROL AER HFA
ID	20190207	66993001968	ALBUTEROL AER HFA
VT	20190207	66993001968	ALBUTEROL AER HFA
TX	20190207	66993001968	ALBUTEROL AER HFA
IL	20190207	66993001968	ALBUTEROL AER HFA
NC	20190207	66993001968	ALBUTEROL AER HFA
OH	20190207	66993001968	ALBUTEROL AER HFA
NJ	20190207	66993001968	ALBUTEROL AER HFA
AZ	20190207	66993001968	ALBUTEROL AER HFA
OR	20190207	66993001968	ALBUTEROL AER HFA
MO	20190207	66993001968	ALBUTEROL AER HFA
MN	20190207	66993001968	ALBUTEROL AER HFA

STATE	DATE FILL	NDC	DRUG
WI	20190207	66993001968	ALBUTEROL AER HFA
WI	20190207	66993001968	ALBUTEROL AER HFA
CA	20190207	66993001968	ALBUTEROL AER HFA
MS	20190207	66993001968	ALBUTEROL AER HFA
IA	20190207	66993001968	ALBUTEROL AER HFA
MD	20190207	66993001968	ALBUTEROL AER HFA
FL	20190207	66993001968	ALBUTEROL AER HFA
NE	20190207	66993001968	ALBUTEROL AER HFA
MS	20190207	66993001968	ALBUTEROL AER HFA
OH	20190207	66993001968	ALBUTEROL AER HFA
OH	20190207	66993001968	ALBUTEROL AER HFA
MS	20190207	66993001968	ALBUTEROL AER HFA
TX	20190207	66993001968	ALBUTEROL AER HFA
PA	20190207	66993001968	ALBUTEROL AER HFA
TX	20190207	66993001968	ALBUTEROL AER HFA
CA	20190207	66993001968	ALBUTEROL AER HFA
FL	20190207	66993001968	ALBUTEROL AER HFA
VA	20190207	66993001968	ALBUTEROL AER HFA
SC	20190207	66993001968	ALBUTEROL AER HFA
FL	20190207	66993001968	ALBUTEROL AER HFA
WA	20190207	66993001968	ALBUTEROL AER HFA
NY	20190207	66993001968	ALBUTEROL AER HFA
CA	20190207	66993001968	ALBUTEROL AER HFA
NM	20190207	66993001968	ALBUTEROL AER HFA
TX	20190207	66993001968	ALBUTEROL AER HFA
SC	20190207	66993001968	ALBUTEROL AER HFA
TX	20190207	66993001968	ALBUTEROL AER HFA
TX	20190207	66993001968	ALBUTEROL AER HFA
NM	20190208	66993001968	ALBUTEROL AER HFA
NY	20190208	66993001968	ALBUTEROL AER HFA
NH	20190208	66993001968	ALBUTEROL AER HFA
PA	20190208	66993001968	ALBUTEROL AER HFA
PA	20190208	66993001968	ALBUTEROL AER HFA
TX	20190208	66993001968	ALBUTEROL AER HFA
WA	20190208	66993001968	ALBUTEROL AER HFA
IA	20190208	66993001968	ALBUTEROL AER HFA
CA	20190208	66993001968	ALBUTEROL AER HFA
NJ	20190208	66993001968	ALBUTEROL AER HFA
WA	20190208	66993001968	ALBUTEROL AER HFA
MD	20190208	66993001968	ALBUTEROL AER HFA

STATE	DATE FILL	NDC	DRUG
AZ	20190208	66993001968	ALBUTEROL AER HFA
MI	20190208	66993001968	ALBUTEROL AER HFA
MN	20190208	66993001968	ALBUTEROL AER HFA
NY	20190208	66993001968	ALBUTEROL AER HFA
OH	20190208	66993001968	ALBUTEROL AER HFA
PA	20190208	66993001968	ALBUTEROL AER HFA
FL	20190208	66993001968	ALBUTEROL AER HFA
WY	20190208	66993001968	ALBUTEROL AER HFA
IA	20190208	66993001968	ALBUTEROL AER HFA
NY	20190208	66993001968	ALBUTEROL AER HFA
OR	20190208	66993001968	ALBUTEROL AER HFA
MN	20190208	66993001968	ALBUTEROL AER HFA
TX	20190208	66993001968	ALBUTEROL AER HFA
MN	20190208	66993001968	ALBUTEROL AER HFA
TN	20190208	66993001968	ALBUTEROL AER HFA
SC	20190208	66993001968	ALBUTEROL AER HFA
KS	20190208	66993001968	ALBUTEROL AER HFA
OH	20190208	66993001968	ALBUTEROL AER HFA
GA	20190208	66993001968	ALBUTEROL AER HFA
WV	20190208	66993001968	ALBUTEROL AER HFA
MN	20190208	66993001968	ALBUTEROL AER HFA
MN	20190208	66993001968	ALBUTEROL AER HFA
NC	20190208	66993001968	ALBUTEROL AER HFA
CA	20190208	66993001968	ALBUTEROL AER HFA
CA	20190208	66993001968	ALBUTEROL AER HFA
CO	20190208	66993001968	ALBUTEROL AER HFA
MO	20190208	66993001968	ALBUTEROL AER HFA
NY	20190208	66993001968	ALBUTEROL AER HFA
CA	20190208	66993001968	ALBUTEROL AER HFA
CA	20190208	66993001968	ALBUTEROL AER HFA
CA	20190208	66993001968	ALBUTEROL AER HFA
CO	20190208	66993001968	ALBUTEROL AER HFA
SC	20190208	66993001968	ALBUTEROL AER HFA
NY	20190208	66993001968	ALBUTEROL AER HFA
KY	20190208	66993001968	ALBUTEROL AER HFA
CA	20190208	66993001968	ALBUTEROL AER HFA
IL	20190208	66993001968	ALBUTEROL AER HFA
MA	20190208	66993001968	ALBUTEROL AER HFA
AR	20190208	66993001968	ALBUTEROL AER HFA
GA	20190208	66993001968	ALBUTEROL AER HFA

STATE	DATE FILL	NDC	DRUG
MN	20190208	66993001968	ALBUTEROL AER HFA
MI	20190208	66993001968	ALBUTEROL AER HFA
MS	20190208	66993001968	ALBUTEROL AER HFA
FL	20190208	66993001968	ALBUTEROL AER HFA
NJ	20190208	66993001968	ALBUTEROL AER HFA
IN	20190208	66993001968	ALBUTEROL AER HFA
TX	20190208	66993001968	ALBUTEROL AER HFA
MN	20190208	66993001968	ALBUTEROL AER HFA
NY	20190208	66993001968	ALBUTEROL AER HFA
MD	20190208	66993001968	ALBUTEROL AER HFA
IN	20190208	66993001968	ALBUTEROL AER HFA
MI	20190208	66993001968	ALBUTEROL AER HFA
MI	20190208	66993001968	ALBUTEROL AER HFA
NC	20190208	66993001968	ALBUTEROL AER HFA
CA	20190208	66993001968	ALBUTEROL AER HFA
FL	20190208	66993001968	ALBUTEROL AER HFA
CA	20190208	66993001968	ALBUTEROL AER HFA
NC	20190208	66993001968	ALBUTEROL AER HFA
TX	20190208	66993001968	ALBUTEROL AER HFA
IN	20190208	66993001968	ALBUTEROL AER HFA
IL	20190208	66993001968	ALBUTEROL AER HFA
IL	20190208	66993001968	ALBUTEROL AER HFA
KS	20190208	66993001968	ALBUTEROL AER HFA
NY	20190208	66993001968	ALBUTEROL AER HFA
TN	20190208	66993001968	ALBUTEROL AER HFA
TN	20190208	66993001968	ALBUTEROL AER HFA
GA	20190208	66993001968	ALBUTEROL AER HFA
PA	20190208	66993001968	ALBUTEROL AER HFA
IL	20190209	66993001968	ALBUTEROL AER HFA
DE	20190209	66993001968	ALBUTEROL AER HFA
FL	20190209	66993001968	ALBUTEROL AER HFA
NY	20190209	66993001968	ALBUTEROL AER HFA
TX	20190209	66993001968	ALBUTEROL AER HFA
SC	20190209	66993001968	ALBUTEROL AER HFA
NM	20190209	66993001968	ALBUTEROL AER HFA
SD	20190209	66993001968	ALBUTEROL AER HFA
VA	20190209	66993001968	ALBUTEROL AER HFA
AR	20190209	66993001968	ALBUTEROL AER HFA
WA	20190209	66993001968	ALBUTEROL AER HFA
IL	20190209	66993001968	ALBUTEROL AER HFA

STATE	DATE FILL	NDC	DRUG
NC	20190209	66993001968	ALBUTEROL AER HFA
TN	20190209	66993001968	ALBUTEROL AER HFA
LA	20190209	66993001968	ALBUTEROL AER HFA
NM	20190209	66993001968	ALBUTEROL AER HFA
MN	20190209	66993001968	ALBUTEROL AER HFA
CA	20190209	66993001968	ALBUTEROL AER HFA
SC	20190209	66993001968	ALBUTEROL AER HFA
NV	20190209	66993001968	ALBUTEROL AER HFA
MN	20190209	66993001968	ALBUTEROL AER HFA
NY	20190209	66993001968	ALBUTEROL AER HFA
IA	20190209	66993001968	ALBUTEROL AER HFA
OH	20190209	66993001968	ALBUTEROL AER HFA
WI	20190209	66993001968	ALBUTEROL AER HFA
VA	20190209	66993001968	ALBUTEROL AER HFA
MI	20190209	66993001968	ALBUTEROL AER HFA
MO	20190209	66993001968	ALBUTEROL AER HFA
OH	20190209	66993001968	ALBUTEROL AER HFA
CA	20190209	66993001968	ALBUTEROL AER HFA
AR	20190209	66993001968	ALBUTEROL AER HFA
IN	20190209	66993001968	ALBUTEROL AER HFA
SC	20190209	66993001968	ALBUTEROL AER HFA
SC	20190209	66993001968	ALBUTEROL AER HFA
IN	20190209	66993001968	ALBUTEROL AER HFA
FL	20190210	66993001968	ALBUTEROL AER HFA
GA	20190210	66993001968	ALBUTEROL AER HFA
CA	20190210	66993001968	ALBUTEROL AER HFA
MI	20190210	66993001968	ALBUTEROL AER HFA
RI	20190210	66993001968	ALBUTEROL AER HFA
GA	20190210	66993001968	ALBUTEROL AER HFA
NC	20190210	66993001968	ALBUTEROL AER HFA
NC	20190210	66993001968	ALBUTEROL AER HFA
GA	20190210	66993001968	ALBUTEROL AER HFA
NC	20190210	66993001968	ALBUTEROL AER HFA
MS	20190210	66993001968	ALBUTEROL AER HFA
CA	20190210	66993001968	ALBUTEROL AER HFA
AR	20190210	66993001968	ALBUTEROL AER HFA
GA	20190210	66993001968	ALBUTEROL AER HFA
FL	20190210	66993001968	ALBUTEROL AER HFA
FL	20190210	66993001968	ALBUTEROL AER HFA
OR	20190210	66993001968	ALBUTEROL AER HFA

STATE	DATE FILL	NDC	DRUG
AR	20190210	66993001968	ALBUTEROL AER HFA
CA	20190210	66993001968	ALBUTEROL AER HFA
TN	20190210	66993001968	ALBUTEROL AER HFA
IL	20190210	66993001968	ALBUTEROL AER HFA
MA	20190210	66993001968	ALBUTEROL AER HFA
PA	20190210	66993001968	ALBUTEROL AER HFA
FL	20190210	66993001968	ALBUTEROL AER HFA
FL	20190210	66993001968	ALBUTEROL AER HFA
MD	20190211	66993001968	ALBUTEROL AER HFA
MI	20190211	66993001968	ALBUTEROL AER HFA
MI	20190211	66993001968	ALBUTEROL AER HFA
AZ	20190211	66993001968	ALBUTEROL AER HFA
IN	20190211	66993001968	ALBUTEROL AER HFA
HI	20190211	66993001968	ALBUTEROL AER HFA
FL	20190211	66993001968	ALBUTEROL AER HFA
IA	20190211	66993001968	ALBUTEROL AER HFA
NJ	20190211	66993001968	ALBUTEROL AER HFA
IA	20190211	66993001968	ALBUTEROL AER HFA
RI	20190211	66993001968	ALBUTEROL AER HFA
MO	20190211	66993001968	ALBUTEROL AER HFA
SC	20190211	66993001968	ALBUTEROL AER HFA
TX	20190211	66993001968	ALBUTEROL AER HFA
TX	20190211	66993001968	ALBUTEROL AER HFA
SC	20190211	66993001968	ALBUTEROL AER HFA
FL	20190211	66993001968	ALBUTEROL AER HFA
FL	20190211	66993001968	ALBUTEROL AER HFA
NE	20190211	66993001968	ALBUTEROL AER HFA
FL	20190211	66993001968	ALBUTEROL AER HFA
NY	20190211	66993001968	ALBUTEROL AER HFA
VA	20190211	66993001968	ALBUTEROL AER HFA
MN	20190211	66993001968	ALBUTEROL AER HFA
FL	20190211	66993001968	ALBUTEROL AER HFA
PA	20190211	66993001968	ALBUTEROL AER HFA
NH	20190211	66993001968	ALBUTEROL AER HFA
SC	20190211	66993001968	ALBUTEROL AER HFA
IL	20190211	66993001968	ALBUTEROL AER HFA
NY	20190211	66993001968	ALBUTEROL AER HFA
MN	20190211	66993001968	ALBUTEROL AER HFA
MD	20190211	66993001968	ALBUTEROL AER HFA
NM	20190211	66993001968	ALBUTEROL AER HFA

STATE	DATE FILL	NDC	DRUG
KY	20190211	66993001968	ALBUTEROL AER HFA
AR	20190211	66993001968	ALBUTEROL AER HFA
MS	20190211	66993001968	ALBUTEROL AER HFA
SC	20190211	66993001968	ALBUTEROL AER HFA
MI	20190211	66993001968	ALBUTEROL AER HFA
NY	20190211	66993001968	ALBUTEROL AER HFA
MN	20190211	66993001968	ALBUTEROL AER HFA
VA	20190211	66993001968	ALBUTEROL AER HFA
IL	20190211	66993001968	ALBUTEROL AER HFA
ID	20190211	66993001968	ALBUTEROL AER HFA
NE	20190211	66993001968	ALBUTEROL AER HFA
SC	20190211	66993001968	ALBUTEROL AER HFA
OR	20190211	66993001968	ALBUTEROL AER HFA
IL	20190211	66993001968	ALBUTEROL AER HFA
TX	20190211	66993001968	ALBUTEROL AER HFA
IL	20190211	66993001968	ALBUTEROL AER HFA
MN	20190211	66993001968	ALBUTEROL AER HFA
MD	20190211	66993001968	ALBUTEROL AER HFA
NY	20190211	66993001968	ALBUTEROL AER HFA
MI	20190211	66993001968	ALBUTEROL AER HFA
TX	20190211	66993001968	ALBUTEROL AER HFA
SD	20190211	66993001968	ALBUTEROL AER HFA
FL	20190211	66993001968	ALBUTEROL AER HFA
CA	20190211	66993001968	ALBUTEROL AER HFA
MN	20190211	66993001968	ALBUTEROL AER HFA
MI	20190211	66993001968	ALBUTEROL AER HFA
SC	20190211	66993001968	ALBUTEROL AER HFA
MI	20190211	66993001968	ALBUTEROL AER HFA
MI	20190211	66993001968	ALBUTEROL AER HFA
KY	20190211	66993001968	ALBUTEROL AER HFA
MI	20190211	66993001968	ALBUTEROL AER HFA
CA	20190211	66993001968	ALBUTEROL AER HFA
IA	20190211	66993001968	ALBUTEROL AER HFA
MS	20190211	66993001968	ALBUTEROL AER HFA
OH	20190211	66993001968	ALBUTEROL AER HFA
FL	20190211	66993001968	ALBUTEROL AER HFA
WA	20190211	66993001968	ALBUTEROL AER HFA
LA	20190211	66993001968	ALBUTEROL AER HFA
LA	20190211	66993001968	ALBUTEROL AER HFA
MO	20190211	66993001968	ALBUTEROL AER HFA

STATE	DATE FILL	NDC	DRUG
PA	20190211	66993001968	ALBUTEROL AER HFA
WA	20190211	66993001968	ALBUTEROL AER HFA
SC	20190211	66993001968	ALBUTEROL AER HFA
FL	20190211	66993001968	ALBUTEROL AER HFA
KS	20190211	66993001968	ALBUTEROL AER HFA
HI	20190211	66993001968	ALBUTEROL AER HFA
AZ	20190211	66993001968	ALBUTEROL AER HFA
FL	20190211	66993001968	ALBUTEROL AER HFA
KY	20190211	66993001968	ALBUTEROL AER HFA
SD	20190211	66993001968	ALBUTEROL AER HFA
PA	20190211	66993001968	ALBUTEROL AER HFA
OH	20190211	66993001968	ALBUTEROL AER HFA
FL	20190211	66993001968	ALBUTEROL AER HFA
TX	20190211	66993001968	ALBUTEROL AER HFA
FL	20190211	66993001968	ALBUTEROL AER HFA
MD	20190211	66993001968	ALBUTEROL AER HFA
FL	20190211	66993001968	ALBUTEROL AER HFA
CA	20190211	66993001968	ALBUTEROL AER HFA
MI	20190211	66993001968	ALBUTEROL AER HFA
FL	20190211	66993001968	ALBUTEROL AER HFA
MS	20190211	66993001968	ALBUTEROL AER HFA
MI	20190211	66993001968	ALBUTEROL AER HFA
MI	20190211	66993001968	ALBUTEROL AER HFA
MI	20190211	66993001968	ALBUTEROL AER HFA
WI	20190211	66993001968	ALBUTEROL AER HFA
MN	20190211	66993001968	ALBUTEROL AER HFA
GA	20190211	66993001968	ALBUTEROL AER HFA
MS	20190211	66993001968	ALBUTEROL AER HFA
MN	20190211	66993001968	ALBUTEROL AER HFA
OK	20190211	66993001968	ALBUTEROL AER HFA
SC	20190211	66993001968	ALBUTEROL AER HFA
NY	20190211	66993001968	ALBUTEROL AER HFA
FL	20190211	66993001968	ALBUTEROL AER HFA
OH	20190211	66993001968	ALBUTEROL AER HFA
PA	20190211	66993001968	ALBUTEROL AER HFA
IL	20190211	66993001968	ALBUTEROL AER HFA
IL	20190211	66993001968	ALBUTEROL AER HFA
NC	20190211	66993001968	ALBUTEROL AER HFA
IL	20190211	66993001968	ALBUTEROL AER HFA
IL	20190211	66993001968	ALBUTEROL AER HFA

STATE	DATE FILL	NDC	DRUG
IL	20190211	66993001968	ALBUTEROL AER HFA
ME	20190211	66993001968	ALBUTEROL AER HFA
MI	20190211	66993001968	ALBUTEROL AER HFA
SD	20190211	66993001968	ALBUTEROL AER HFA
MD	20190211	66993001968	ALBUTEROL AER HFA
WI	20190211	66993001968	ALBUTEROL AER HFA
LA	20190211	66993001968	ALBUTEROL AER HFA
FL	20190211	66993001968	ALBUTEROL AER HFA
GA	20190211	66993001968	ALBUTEROL AER HFA
IL	20190212	66993001968	ALBUTEROL AER HFA
CA	20190212	66993001968	ALBUTEROL AER HFA
CA	20190212	66993001968	ALBUTEROL AER HFA
GA	20190212	66993001968	ALBUTEROL AER HFA
LA	20190212	66993001968	ALBUTEROL AER HFA
AL	20190212	66993001968	ALBUTEROL AER HFA
TX	20190212	66993001968	ALBUTEROL AER HFA
IN	20190212	66993001968	ALBUTEROL AER HFA
IN	20190212	66993001968	ALBUTEROL AER HFA
NJ	20190212	66993001968	ALBUTEROL AER HFA
NY	20190212	66993001968	ALBUTEROL AER HFA
IL	20190212	66993001968	ALBUTEROL AER HFA
NC	20190212	66993001968	ALBUTEROL AER HFA
VT	20190212	66993001968	ALBUTEROL AER HFA
TN	20190212	66993001968	ALBUTEROL AER HFA
NC	20190212	66993001968	ALBUTEROL AER HFA
TX	20190212	66993001968	ALBUTEROL AER HFA
OH	20190212	66993001968	ALBUTEROL AER HFA
ID	20190212	66993001968	ALBUTEROL AER HFA
TX	20190212	66993001968	ALBUTEROL AER HFA
SC	20190212	66993001968	ALBUTEROL AER HFA
IN	20190212	66993001968	ALBUTEROL AER HFA
CA	20190212	66993001968	ALBUTEROL AER HFA
WV	20190212	66993001968	ALBUTEROL AER HFA
NC	20190212	66993001968	ALBUTEROL AER HFA
NY	20190212	66993001968	ALBUTEROL AER HFA
NY	20190212	66993001968	ALBUTEROL AER HFA
IL	20190212	66993001968	ALBUTEROL AER HFA
SC	20190212	66993001968	ALBUTEROL AER HFA
CT	20190212	66993001968	ALBUTEROL AER HFA
PA	20190212	66993001968	ALBUTEROL AER HFA

STATE	DATE FILL	NDC	DRUG
OK	20190212	66993001968	ALBUTEROL AER HFA
IL	20190212	66993001968	ALBUTEROL AER HFA
KY	20190212	66993001968	ALBUTEROL AER HFA
GA	20190212	66993001968	ALBUTEROL AER HFA
TX	20190212	66993001968	ALBUTEROL AER HFA
OR	20190212	66993001968	ALBUTEROL AER HFA
PA	20190212	66993001968	ALBUTEROL AER HFA
AR	20190212	66993001968	ALBUTEROL AER HFA
MN	20190212	66993001968	ALBUTEROL AER HFA
IL	20190212	66993001968	ALBUTEROL AER HFA
WA	20190212	66993001968	ALBUTEROL AER HFA
CA	20190212	66993001968	ALBUTEROL AER HFA
MO	20190212	66993001968	ALBUTEROL AER HFA
OH	20190212	66993001968	ALBUTEROL AER HFA
IA	20190212	66993001968	ALBUTEROL AER HFA
NY	20190212	66993001968	ALBUTEROL AER HFA
MA	20190212	66993001968	ALBUTEROL AER HFA
KS	20190212	66993001968	ALBUTEROL AER HFA
CA	20190212	66993001968	ALBUTEROL AER HFA
MS	20190212	66993001968	ALBUTEROL AER HFA
IL	20190212	66993001968	ALBUTEROL AER HFA
KY	20190212	66993001968	ALBUTEROL AER HFA
IL	20190212	66993001968	ALBUTEROL AER HFA
IN	20190212	66993001968	ALBUTEROL AER HFA
NJ	20190212	66993001968	ALBUTEROL AER HFA
NM	20190212	66993001968	ALBUTEROL AER HFA
MI	20190212	66993001968	ALBUTEROL AER HFA
FL	20190212	66993001968	ALBUTEROL AER HFA
SC	20190212	66993001968	ALBUTEROL AER HFA
MT	20190212	66993001968	ALBUTEROL AER HFA
AR	20190212	66993001968	ALBUTEROL AER HFA
CA	20190212	66993001968	ALBUTEROL AER HFA
MI	20190212	66993001968	ALBUTEROL AER HFA
WV	20190212	66993001968	ALBUTEROL AER HFA
CA	20190212	66993001968	ALBUTEROL AER HFA
IL	20190212	66993001968	ALBUTEROL AER HFA
PA	20190212	66993001968	ALBUTEROL AER HFA
NY	20190212	66993001968	ALBUTEROL AER HFA
WI	20190212	66993001968	ALBUTEROL AER HFA
WV	20190212	66993001968	ALBUTEROL AER HFA

STATE	DATE FILL	NDC	DRUG
TX	20190212	66993001968	ALBUTEROL AER HFA
GA	20190212	66993001968	ALBUTEROL AER HFA
SD	20190212	66993001968	ALBUTEROL AER HFA
IL	20190212	66993001968	ALBUTEROL AER HFA
NY	20190212	66993001968	ALBUTEROL AER HFA
IL	20190212	66993001968	ALBUTEROL AER HFA
IL	20190212	66993001968	ALBUTEROL AER HFA
KY	20190212	66993001968	ALBUTEROL AER HFA
TN	20190212	66993001968	ALBUTEROL AER HFA
KY	20190212	66993001968	ALBUTEROL AER HFA
IL	20190212	66993001968	ALBUTEROL AER HFA
ID	20190212	66993001968	ALBUTEROL AER HFA
CA	20190212	66993001968	ALBUTEROL AER HFA
SC	20190212	66993001968	ALBUTEROL AER HFA
FL	20190212	66993001968	ALBUTEROL AER HFA
IL	20190212	66993001968	ALBUTEROL AER HFA
OK	20190212	66993001968	ALBUTEROL AER HFA
IN	20190212	66993001968	ALBUTEROL AER HFA
MN	20190212	66993001968	ALBUTEROL AER HFA
CA	20190212	66993001968	ALBUTEROL AER HFA
LA	20190212	66993001968	ALBUTEROL AER HFA
CA	20190212	66993001968	ALBUTEROL AER HFA
OH	20190212	66993001968	ALBUTEROL AER HFA
IN	20190212	66993001968	ALBUTEROL AER HFA
PA	20190212	66993001968	ALBUTEROL AER HFA
VA	20190212	66993001968	ALBUTEROL AER HFA
SC	20190212	66993001968	ALBUTEROL AER HFA
NY	20190212	66993001968	ALBUTEROL AER HFA
IL	20190212	66993001968	ALBUTEROL AER HFA
CA	20190212	66993001968	ALBUTEROL AER HFA
AR	20190212	66993001968	ALBUTEROL AER HFA
MO	20190212	66993001968	ALBUTEROL AER HFA
OR	20190212	66993001968	ALBUTEROL AER HFA
NM	20190212	66993001968	ALBUTEROL AER HFA
CO	20190212	66993001968	ALBUTEROL AER HFA
IN	20190212	66993001968	ALBUTEROL AER HFA
NY	20190212	66993001968	ALBUTEROL AER HFA
NY	20190212	66993001968	ALBUTEROL AER HFA
MD	20190212	66993001968	ALBUTEROL AER HFA
AR	20190212	66993001968	ALBUTEROL AER HFA

<u>STATE</u>	<u>DATE FILL</u>	<u>NDC</u>	<u>DRUG</u>
IA	20190213	66993001968	ALBUTEROL AER HFA
KY	20190213	66993001968	ALBUTEROL AER HFA
FL	20190213	66993001968	ALBUTEROL AER HFA
IL	20190213	66993001968	ALBUTEROL AER HFA
PA	20190213	66993001968	ALBUTEROL AER HFA
AL	20190213	66993001968	ALBUTEROL AER HFA
MS	20190213	66993001968	ALBUTEROL AER HFA
GA	20190213	66993001968	ALBUTEROL AER HFA
WI	20190213	66993001968	ALBUTEROL AER HFA
MA	20190213	66993001968	ALBUTEROL AER HFA
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KS	20190213	66993001968	ALBUTEROL AER HFA
FL	20190213	66993001968	ALBUTEROL AER HFA
NY	20190213	66993001968	ALBUTEROL AER HFA
OH	20190213	66993001968	ALBUTEROL AER HFA
FL	20190213	66993001968	ALBUTEROL AER HFA
FL	20190213	66993001968	ALBUTEROL AER HFA
FL	20190213	66993001968	ALBUTEROL AER HFA
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NY	20190213	66993001968	ALBUTEROL AER HFA
WA	20190213	66993001968	ALBUTEROL AER HFA

EXHIBIT 66

MED D - CANASA® RECTAL SUPPOSITORY Generic Not Available for SilverScript Choice, Plus, and Allure (PDP) Plans Until Further Notice <Document_Number>

[Overview](#)

[Background](#)

[Rationale](#)

[What does this mean for the beneficiary?](#)

[Effects of this Strategy on Beneficiaries](#)

[FAQs](#)

[Log Activity](#)




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Grievance Standard Verbiage:

Grievance Standard Verbiage (for use in Discussion with Beneficiary) section in [MED D Care - Grievances in PeopleSafe and MedHOK](#)

Legend:

Icon	Explanation
	Updates to information. The icon should be followed by the date of update. Note: Only the last update will be identified.
	Indicates Important or Urgent information
	Indicates a Talk Track

Overview

CANASA® RECTAL SUPPOSITORY is a branded prescription drug commonly used for the treatment of Crohn's disease, a type of inflammatory bowel disease. This prescription drug was recently launched in its generic form, mesalamine rectal suppository. The generic form of CANASA RECTAL SUPPOSITORY is not available on SilverScript Choice, Plus, or Allure (PDP) plans until further notice.

CANASA RECTAL SUPPOSITORY will be MAINTAINED on the Non-Preferred Drug Tier (Tier 4) in 2019 on the formularies for SilverScript Choice, Plus, and Allure beneficiaries. The generic, mesalamine rectal suppository, will **NOT** be added to the formularies.

This applies only to SilverScript Choice, Plus, and Allure beneficiaries in 2019.

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Background

Generic prescription drugs are typically the lowest-cost option when compared to branded prescription drugs. SilverScript **promotes the use of generic prescription drugs** to help plan beneficiaries save money.

- During the initial launch phase for the generic, there will be few manufacturers marketing the generic and the cost of the generic is expected to be relatively high.
- To help keep out-of-pocket costs low, SilverScript is retaining brand CANASA® RECTAL SUPPOSITORY on its formulary on Non-Preferred Drug Tier (Tier 4). CANASA is eligible for a manufacturer discount in the coverage gap.
- SilverScript will continue to keep the brand version of CANASA RECTAL SUPPOSITORY on the formulary and will **NOT** be adding the generic version until further notice.

Network Pharmacies were also informed of this update.

NOTE: SilverScript Employer PDP Plans are being handled differently.

- **SilverScript Choice, Plus, and Allure Plans**

The generic version of CANASA RECTAL SUPPOSITORY (mesalamine rectal suppository) will **NOT** be added to the SilverScript formularies for SilverScript Choice, Plus, and Allure plans in 2019.

- **SilverScript Employer PDP Plans**

Employer PDP Plans have added the generic (mesalamine rectal suppository) to their formulary for 2019. Some plans will continue cover the brand in 2019.

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Rationale

The goal of this document is to prepare the MED D Customer Care Representative (CCR) for potential inbound questions from the beneficiary regarding the availability of mesalamine rectal suppository and the non-covered status for this prescription drug on SilverScript Plans.

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What does this mean for the beneficiary?

Retaining brand CANASA RECTAL SUPPOSITORY on Non-Preferred Drug Tier (Tier 4) can help keep out-of-pocket costs low for SilverScript beneficiaries.

NOTE: The generic equivalent mesalamine rectal suppository is **NOT** be on the formulary until further notice.

- Beneficiaries have the option to request an exception if they wish to obtain mesalamine rectal suppository.
 - However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.

- Brand CANASA RECTAL SUPPOSITORY is available at the Non-Preferred Drug Tier (Tier 4) copay/coinsurance, so if the request for the generic is granted, the beneficiary would pay the amount associated with the plan's exception tier. This may be a different cost than the brand.

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Effects of this Strategy on Beneficiaries

- Beneficiaries will continue to receive the brand CANASA RECTAL SUPPOSITORY at the Non-Preferred Drug Tier (Tier 4) cost share.
- The CCR may receive calls from MED D beneficiaries who are confused about the lack of generic version availability of the prescription drug. Refer to the [FAQs](#) section of this document for appropriate responses.

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FAQs

The frequently asked questions below will assist the CCR when addressing incoming calls regarding CANASA RECTAL SUPPOSITORY.


NOTE: These specifics apply to non-LIS beneficiaries. See specific Q&A at end of this FAQ section for information specific to LIS beneficiaries.

Question	Answer		
Will CANASA RECTAL SUPPOSITORY cost more than mesalamine rectal suppository in any stage of the Medicare D benefit for non-LIS beneficiaries?	SAY: <ul style="list-style-type: none">This will vary based on your Plan and which Medicare Part D coverage stage you currently are in (e.g., Deductible, Initial Coverage Limits, Coverage Gap or Catastrophic). CCR Process Note: The CCR will review the following grid for information on the anticipated costs of CANASA RECTAL SUPPOSITORY vs. mesalamine rectal suppository during the mesalamine rectal suppository initial launch period:		
	<table><tr><td>Deductible Stage for non-LIS beneficiaries:</td><td>SilverScript Choice , Plus, and Allure beneficiaries:<ul style="list-style-type: none">In 2019, no deductible except for Choice Plan beneficiaries who will have a \$100 annual deductible for drugs in Tiers 3 to 5 for beneficiaries residing in Colorado, Georgia, or Texas; Choice beneficiaries residing in Arizona, South Carolina, or Alaska will have a \$415 deductible for drugs in Tiers 3 to 5. SilverScript Plus and Allure Plans are not available in Alaska.<p>Move to response below in Initial Coverage Limits Stage.</p></td></tr></table>	Deductible Stage for non-LIS beneficiaries:	SilverScript Choice , Plus, and Allure beneficiaries: <ul style="list-style-type: none">In 2019, no deductible except for Choice Plan beneficiaries who will have a \$100 annual deductible for drugs in Tiers 3 to 5 for beneficiaries residing in Colorado, Georgia, or Texas; Choice beneficiaries residing in Arizona, South Carolina, or Alaska will have a \$415 deductible for drugs in Tiers 3 to 5. SilverScript Plus and Allure Plans are not available in Alaska. <p>Move to response below in Initial Coverage Limits Stage.</p>
	Deductible Stage for non-LIS beneficiaries:	SilverScript Choice , Plus, and Allure beneficiaries: <ul style="list-style-type: none">In 2019, no deductible except for Choice Plan beneficiaries who will have a \$100 annual deductible for drugs in Tiers 3 to 5 for beneficiaries residing in Colorado, Georgia, or Texas; Choice beneficiaries residing in Arizona, South Carolina, or Alaska will have a \$415 deductible for drugs in Tiers 3 to 5. SilverScript Plus and Allure Plans are not available in Alaska. <p>Move to response below in Initial Coverage Limits Stage.</p>	
Initial Coverage Limits (ICL) Stage for non-LIS beneficiaries:	SAY: <ul style="list-style-type: none">Maybe.You will continue to pay your current Non-Preferred Drug Tier (Tier 4) cost share during the Initial Coverage Limits stage for brand		

		<ul style="list-style-type: none"> • CANASA RECTAL SUPPOSITORY. • Mr. /Mrs. <Beneficiary>, your cost share for brand CANASA RECTAL SUPPOSITORY will be <\$X.XX>. <p>Move to response below in Coverage Gap Stage.</p>
	Coverage Gap Stage for non-LIS beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> • No. • The Coverage Gap Stage (also called the donut hole) is where you will receive significant savings on brand CANASA RECTAL SUPPOSITORY. • The brand name is less expensive than the generic version because of the manufacturer discount on brand name prescription drugs. • In 2019, your cost share in the Coverage Gap Stage is 25% of the price of brand CANASA RECTAL SUPPOSITORY. If the generic were included at this time on the formulary, your cost share would be 37%. <p>Move to response below in Catastrophic Coverage Stage.</p>
	Catastrophic Stage for non-LIS beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> • Yes. • During this stage of the benefit, it is expected that - because of the price of the brand and

		<ul style="list-style-type: none"> generic versions - you will pay 5% of the allowed cost.
Why is the brand-name CANASA RECTAL SUPPOSITORY on the formulary when there is now a generic available?	SAY: <ul style="list-style-type: none"> In this case, the price of the generic version of CANASA RECTAL SUPPOSITORY will likely be similar to the price of the brand version for a minimum of six months, and perhaps longer. There are few manufacturers of the generic version of CANASA RECTAL SUPPOSITORY to drive the price down. Until there are competitors and the price of the generic version goes down, your plan will continue to cover brand-name CANASA RECTAL SUPPOSITORY at the Non-Preferred Drug Tier (Tier 4) cost share in 2019. 	
Why can't I get the generic? Aren't generics less expensive?	SAY: <ul style="list-style-type: none"> When a generic version is first available, it is typically similar in price to the brand version. At this time the generic version, called mesalamine rectal suppository, is not on the formulary. <ul style="list-style-type: none"> You do have the option to request a formulary exception. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level. 	
Will my other copays for other prescription drugs be lowered?	SAY: <ul style="list-style-type: none"> No. You will continue to pay the copay/coinsurance for other brand name and generic prescription drugs at the current benefit cost share. 	

<p>Could there be other brand prescription drugs that this applies to?</p>	<p>SAY:</p> <ul style="list-style-type: none"> • In most cases the generic version of a prescription drug is less expensive than the brand name version and is covered at the lower generic copay. • The exception typically applies during the first few years the generic version of a prescription drug is launched.
<p>How long will CANASA RECTAL SUPPOSITORY remain on the formulary on the Non-Preferred Drug Tier (Tier 4)?</p>	<p>SAY:</p> <ul style="list-style-type: none"> • We anticipate that CANASA RECTAL SUPPOSITORY will remain on the formulary on the Non-Preferred Drug Tier (Tier 4) in 2019 until the price of the generic form of CANASA RECTAL SUPPOSITORY drops. • We anticipate it will be a minimum of six months, however that is based on market conditions not within our control and could change.
<p>What should I do if brand CANASA RECTAL SUPPOSITORY is removed from the formulary during the plan year?</p>	<p>SAY:</p> <ul style="list-style-type: none"> • We will provide you with notification if brand CANASA RECTAL SUPPOSITORY is removed from the formulary during the Plan year. • The type of notification depends on whether you are using the prescription drug and whether the change happens during the plan year or at the beginning of the next plan year. <ul style="list-style-type: none"> ◦ If we make this change during the plan year, and you are using CANASA RECTAL SUPPOSITORY, you will receive written notification of the change in your Explanation of Benefits (EOB). ◦ If we make this change at the beginning of the next plan year, the change will be noted in the formulary included as part of

	<ul style="list-style-type: none"> ○ our Annual Notice of Change (ANOC) packet. ○ You should review your plan's formulary carefully. • If brand CANASA RECTAL SUPPOSITORY is removed from the formulary and you want to continue using brand CANASA RECTAL SUPPOSITORY, you will have the option to request a formulary exception. • However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.
May I, as the beneficiary, request a coverage determination for the generic product?	<p>SAY:</p> <ul style="list-style-type: none"> • Yes, you as the beneficiary may request a coverage determination for mesalamine rectal suppository. <ul style="list-style-type: none"> ○ However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level. <p> Refer to the Med D Care - Coverage Determination/Appeal (New or Status Update) document.</p>
Will mesalamine rectal suppository be added to the formulary during the 2019 plan year?	<p>SAY:</p> <ul style="list-style-type: none"> • The addition of the generic to the formulary will be re-evaluated during the year.
Will CANASA RECTAL SUPPOSITORY cost more than mesalamine rectal suppository in any stage of	<p>CCR Process Note: The CCR will review the following information for LIS beneficiaries on the anticipated costs of CANASA RECTAL SUPPOSITORY vs. mesalamine rectal suppository during the mesalamine rectal suppository initial launch period:</p>

the Medicare Part D benefit for LIS beneficiaries?	For LIS 1 & 2 Beneficiaries:	SAY: <ul style="list-style-type: none"> • Maybe. • In the Catastrophic Coverage Stage of the benefit, you will continue to receive CANASA RECTAL SUPPOSITORY at no cost. • If you have not yet reached the Catastrophic Coverage Stage, you might have to pay your brand name copayment for CANASA RECTAL SUPPOSITORY until you reach the Catastrophic Coverage Stage.
	For LIS 3 Beneficiaries:	SAY: <ul style="list-style-type: none"> • No.
	For LIS 4 Beneficiaries:	SAY: <ul style="list-style-type: none"> • Maybe. • If you are in the Initial Coverage Limits Stage (ICL) or the Post-Initial Coverage Limits Stage of the benefit you will continue to pay your current coinsurance for CANASA RECTAL SUPPOSITORY. • If you are in the Catastrophic Coverage Stage, you will continue to pay the LIS brand name copayment for CANASA RECTAL SUPPOSITORY.

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Log Activity

1003 – Plan Design Education

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Resolution Time

Information = immediate

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Parent SOP

CALL-0048: [Medicare Part D Customer Care Call Center Requirements- CVS Caremark Part D Services, L.L.C.](#)

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EXHIBIT 67

This transcript was exported on Apr 23, 2019 - view latest version [here](#).

Casey: Thank you for choosing SilverScript, this is Casey, how can I help you today?

[REDACTED] Yes, this is [REDACTED]. I have some questions about my SilverScript prescription drugs. I went to my GI doctor on Tuesday and they said I was supposed to have gotten forms from SilverScript that I mail in. Well how in the world am I supposed to mail in forms for my prescription drugs when I don't know all that information, just my doctor does? Or do I take it to the doctor for them to fill out?

Casey: Can I have your zip code please, ma'am?

[REDACTED] Yes. [REDACTED]

Casey: And what type of forms are they?

[REDACTED] I don't know, she said I should have gotten forms in with my SilverScript package. And I do have one, CVS Caremark mail service order form.

Casey: Okay, so you're trying to set up your mail order service.

[REDACTED] Yes.

Casey: Well there's no forms you need to mail out. What needs to happen is, your doctor just has to fax in your prescriptions to us. They can fax them in or they can e-cribe them to us.

[REDACTED] Well I think they were gonna try and do that ... today's Friday, Wednesday. Can you check to see if you've got any prescription drugs [crosstalk 00:01:38]?

Casey: Yes ma'am, do you have your member ID number?

[REDACTED] Do you want my SilverScript, or my Medicare?

Casey: Your SilverScript member ID.

[REDACTED] SilverScript. It says ... ID number is [REDACTED].

Casey: Okay ma'am, give me just a moment to pull up your account.

[REDACTED] Okay.

Casey: Ma'am, if you could verify your date of birth for me.

[REDACTED] [REDACTED]

[REDACTED]

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Transcript by [Rev.com](#)

This transcript was exported on Apr 23, 2019 - view latest version [here](#).

Casey: Thank you for that. Okay. So it looks like we do have an order for Canasa.

[REDACTED] Uh-huh (affirmative).

Casey: On here. Which has a payment exception, so I'd have to get verification from you to process the payment before we can send that out.

[REDACTED] Okay.

Casey: And then we have Omeprazole on file for you. That's the only two medications we have.

[REDACTED] And that's the doctor, that's that one GI doctor, and that's all they were going to send in. So ...

Casey: We have that. Do you need to get that filled?

[REDACTED] Yeah, but I [inaudible 00:03:06], Canasa's a tier four. Can you tell me how much that's gonna cost me, my part?

Casey: Yes ma'am, let me go ahead and put this order in for your Omeprazole and then I can do that for you.

[REDACTED] [inaudible 00:03:31]

Casey: Okay, so I ordered that for you. Now let me check on your [crosstalk 00:03:38].

[REDACTED] What is the, what's the, whatever that was. What's that co-pay?

Casey: The Omeprazole was at no cost to you.

[REDACTED] Oh, really?

Casey: Yes, ma'am.

[REDACTED] Well that might make up for the Canasa.

Casey: The Canasa is very expensive. It says the co-pay amount, \$1711.32.

[REDACTED] For a three month supply, or a one month supply?

Casey: Let me see. It's for a 90 day supply.

[REDACTED]: God, that's terrible, I mean, I'm on Medicare and stuff. I can't afford that but she says there's nothing else ...

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Casey: I was just gonna say, we do have a department that maybe can find a cheaper alternative.

[REDACTED] Okay. Yeah, that'd be great. I can't afford a thousand dollars. That's, what, \$350 a month?

Casey: Yes ma'am. Okay so let me just put you on a brief hold and I'll get you over to that department, so they can see if there's any cheaper alternatives.

[REDACTED] Okay, well, since you're gonna go ahead and do the metha-whatever.

Casey: Yes ma'am, I already put in your order for your other medication.

[REDACTED] Yes, now what do I, and it'll be mailed to me since it's mail order. What about my other drug prescriptions? Like I have Restasis from my eye doctor and I don't go back to them until September. Of course I don't need any right now. And then I have, let's see, what else do I have? I'm sorry. Oh, I have ... Methotrexate from my RA doctor but I don't need any of that right now. So what I do when I do need any is I have my doctor, my RA doctor, fax in a prescription just like my GI doctor did yesterday?

Casey: Yes ma'am, that's correct.

[REDACTED] Okay. Alright, good.

Casey: Okay, so I'm gonna get you over to that other department, okay?

[REDACTED] Okay, thank you.

Automated Voice: You have reached the specialized team. Please hold for the next representative.

Automated Voice: Your call may be monitored or recorded to ensure quality.

Robbie: Thank for for calling the care extension review team, this is Robbie, may I get the plan member's ID number?

Casey: Yes. It is [REDACTED].

Robbie: Okay, and the member's first and last name?

Casey: [REDACTED]

Robbie: And the birthday?

Casey: [REDACTED]

[REDACTED]
Transcript by [Rev.com](#)

This transcript was exported on Apr 23, 2019 - view latest version [here](#).

Robbie: Alright, thank you for that. And can I get your ZID?

Casey: [REDACTED]

Robbie: And your first name?

Casey: Casey.

Robbie: Last initial?

Casey: C as in cat.

Robbie: And your site?

Casey: [REDACTED]

Robbie: And your supervisor?

Casey: [Nikiah 00:08:01].

Robbie: Okay, and how can I help today?

Casey: Okay, [REDACTED] is calling about the medication Canasa, Canasa? She's trying to find a cheaper alternative, she can't afford to pay for that medication.

Robbie: Okay. I'll see what I can do to help her out.

Casey: Alright, and what was your name?

Robbie: It's Robbie.

Casey: Robbie, okay. Can I go ahead and bring her over?

Robbie: Sure.

Casey: Thank you.

Robbie: Thank you.

Casey: [REDACTED]?

[REDACTED] Yes.

Casey: Okay, I do have a Robbie on the line, and they're gonna further assist you with trying to find a cheaper alternative, okay?

[REDACTED]

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[REDACTED]

Okay, thank you for helping me.

Casey:

Yes ma'am, thank you for calling, you both have a wonderful day.

[REDACTED]

Okay, how long, one more question, how long does it take to usually, once you put that order in, for me to get it? When does it ship?

Casey:

The Omeprazole? It has to go through processing for two days and then it'll be shipped out to you.

[REDACTED]

Okay. Alright. Great, thank you.

Casey:

You're welcome.

[REDACTED]

Hello?

Robbie:

Hi [REDACTED]

[REDACTED]

Hello?

Robbie:

My name is Robbie, I'm gonna see what I can do to help you out today, okay?

[REDACTED]

Okay. Your name is Robbie?

Robbie:

Yes ma'am.

[REDACTED]

Okay.

Robbie:

Give me just a second while I access this file, okay?

[REDACTED]

Alright. It's really, your voice is really low. I don't ...

Robbie:

Okay, well I'll try to speak louder.

[REDACTED]

Okay, alrighty. My grandsons are watching cartoons so I turned that down some, too.

[REDACTED]

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EXHIBIT 68

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Rebecca: Good morning, thank you for calling customer care. My name is [Rebecca 00:00:07]. Who do I have the pleasure of speaking with today?

[REDACTED] It's [REDACTED]. I was talking to another lady about 30, 45 minutes ago, and something happened and we got cut-off. But I didn't write her name down. She was helping me.

Rebecca: Okay. Just one moment.

[REDACTED] Can you pull it up and see who I was talking to and transfer me to her?

Rebecca: Well, I can't transfer you to her, but it looks like you were questioning one of the medications that you're taking?

[REDACTED] Yeah, but we've got it straightened out. I mean, I'm gonna have to pay it. One way or the ... If I'm gonna continue on the Canasa, I'm gonna have to pay it. But I'm in a donut hole right now, so once I pay 300 and some more dollars, the medication will go to half price. Right now, it's over \$1700 for a 3-month supply, which people can't afford that!

Rebecca: That's exactly right. I know.

[REDACTED] So she was giving me some numbers to call to get some kind of assistance to help me pay for it. But I mean, I'm gonna get it this first time. I'm gonna give you my charge card number so you can pay it. And then, I can afford \$800-

Rebecca: You're gonna go ahead and do the 30-day supply then for \$364.09, or you want to do the 90-day for \$946?

[REDACTED] I think you're mistaken. It's Canasa, and it's over \$1700. That's what she told me and I said, "Oh!" So she looked it up and it looked like-

Rebecca: Well, I was running a test claim on it.

[REDACTED] Yeah. And she said it looked like, 'cause I was on the phone with her 40 minutes. And she said it looked like when they tried to run the test claimer, it's showing that I've already paid this first \$1700, and I haven't.

Rebecca: Okay. Just bear with me a moment. Let me get back over to that screen. 'Cause I'm seeing a payment exception dated 3/14. So let me go over there and look at that. That's what she's talking about. There's your copay of \$1711.23.

[REDACTED] But see, I've not paid it yet.

Rebecca: Okay. So is that what we want to do? You want to pay that today?

[REDACTED] I guess I have to if I want the medication.

[REDACTED]
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Rebecca: I'm sorry. Yes.

[REDACTED] I hate it. And there's not another medicine. [REDACTED] told me that there was no generic and there's nothing comparable. I've been talking to Silver Script Pharmacies, everything. There's nothing comparable to it, so I have to Canasa.

Rebecca: Okay.

[REDACTED] Or risk the chance of possibly getting cancer down the road.

Rebecca: We don't wanna do that. Okay.

[REDACTED] Nah.

Rebecca: Okay, so let me go back over here. Just bear with me a moment, Hun.

[REDACTED] Okay. That's not a problem. But the next time, when I order it again after three months, it will only be \$800 and some dollars. And that's more affordable.

Rebecca: Right. So are we gonna put this you said on a credit card?

[REDACTED] Yes, ma'am.

Rebecca: Now, is it a MasterCard, Discover, American Express, or Visa?

[REDACTED] It's MasterCard.

Rebecca: Okay. And the card number.

[REDACTED] [REDACTED]

Rebecca: And the expiration date?

[REDACTED] [REDACTED]

Rebecca: Okay, I'm gonna read that card number back to you again. [REDACTED]

[REDACTED] Yes. And the name on the card is [REDACTED]

Rebecca: Okay. All right. Let me go back over here now.

(silence)

Okay, just bear with me a moment.

[REDACTED] Okay.

[REDACTED]
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Rebecca: (silence)

Okay. Just bear with me a moment, Hun.

(silence)

Okay, just bear with me one moment. May I place you on a brief hold for a moment?

Okay.

Rebecca: Thank you.

(silence)

Okay. Thank you for holding.

Okay.

Rebecca: Okay I went in and put in the payment information and everything, but it's showing in dispensing, so you probably have to call back on Monday or Tuesday just to make sure it took your payment. It's in processing right now, so it won't let me apply the payment. But when you call back, I put it in the account as default so it would bill to that card. Just all y'all need to do is call back on Monday or Tuesday to confirm it did. That they processed it on your credit card.

Well, what about the other perscription?

Rebecca: They'll both ship out. They're both in dispensing.

Okay. And I have to call y'all back. Y'all can't call me back and tell me that. Because I hate going through all that automated crap, so y'all can't call me back, somebody and let me know that it went through?

Rebecca: Well, let me do something else over here real quick. Let me look at something else real quick. Bear with me. Because it's showing in process and to ship now. So, it should have accepted my change because it's in dispensing now. And it wouldn't say ship now, it would say ship hold. So everything should be good to go.

Okay. Do you have a confirmation number?

Rebecca: But let me just check something else over here. Hold on. I want to make sure that they're going to notify you it's shipped.

Okay.

Rebecca: So just let me check something.

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[REDACTED] How are you dealing with three dogs?

Speaker 3: I'm ready to take one of 'em back. [inaudible 00:11:46].

[REDACTED] She's a cute little dog [inaudible 00:11:53]. You'll be glad when that person that's taking your attention leaves, too. Won't cha?

Rebecca: Okay.

[REDACTED] Okay.

Rebecca: So, what's it's done. I don't have a confirmation number because it won't assign one while it's in dispensing. I have an order number, but it is showing that when they ship it they'll notify you that they've shipped it and it's on its way. And that will tell you that they put it on there.

[REDACTED] Okay.

Rebecca: They'll give you a call.

[REDACTED] Okay. That'll be good.

Rebecca: No problem. Thank you for calling customer-

[REDACTED] Yeah. I always get calls. I always get calls telling me that it shipped.

Rebecca: Oh, okay. But like I said, we wouldn't know til, because it's in dispensing. But everything's on there like it should be, and it's saying it's to ship now. It's not saying it's on hold, so I-

[REDACTED] Okay. Well, what's my total amount?

Rebecca: Just one second.

[REDACTED] Ma'am?

Rebecca: Just one second, let me get back over there.

[REDACTED] Okay.

Rebecca: Okay, just bear with me a moment. Just bear with me a moment, I'm trying to get back to that screen. It's not wanting me to get there, but we will. Just one moment.

Speaker 3: [inaudible 00:13:42].

[REDACTED] Yeah.

[REDACTED]
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Speaker 3: [inaudible 00:13:43].

Rebecca: It's showing ... What it's processing for is the Canasa Syrup for \$1711.23. And it looks like they were already sending you a bill on the Omeprazole for \$23.22.

[REDACTED] Sending me a bill? What do you mean? In the mail?

Rebecca: With your Omeprazole, they would be sending a bill for the \$23.22.

[REDACTED] So I'm not going to get charged \$23.22 today on my credit card?

Rebecca: No, ma'am.

[REDACTED] I'll just be charged the \$1711.23.

Rebecca: Yes, ma'am.

[REDACTED] Okay.

Rebecca: Is there anything else I can do for you today?

[REDACTED] No, not unless you can get me that Canasa a whole lot cheaper.

Rebecca: Oh, I sure wished I could. I absolutely do.

[REDACTED] Yeah. All right, thank you.

Rebecca: You have a wonderful day and thank you for calling customer care.

[REDACTED] Okay. Bye.

Rebecca: Bye-bye.

[REDACTED] Now, I have this [inaudible 00:14:55].

EXHIBIT 69

This transcript was exported on Apr 23, 2019 - view latest version [here](#).

Robbie: Thank you for calling the care extension review team. This is Robbie. May I get the plan member's ID number?

Casey: Yes. It is [REDACTED]

Robbie: Okay, and the member's first and last name.

Casey: [REDACTED]

Robbie: And the birthday.

Casey: [REDACTED]

Robbie: Alright. Thank you for that, and can I get your ZID?

Casey: [REDACTED]

Robbie: And your first name?

Casey: Casey.

Robbie: Last initial?

Casey: C as in cat.

Robbie: And your site?

Casey: [REDACTED]

Robbie: And your supervisor?

Casey: Nikea.

Robbie: Okay, and how can I help today?

Casey: Okay. [REDACTED] is calling about the medication Canasa. She's trying to find a cheaper alternative. She can't afford to pay for that medication.

Robbie: Okay. I'll see what I can do to help her out.

Casey: Alright, and what was your name?

Robbie: It's Robbie.

Casey: Robbie. Okay, can I go ahead and bring her over?

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[REDACTED]
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Robbie: Sure.

Casey: Thank you.

Robbie: Thank you.

Casey: [REDACTED]

[REDACTED]: Yes.

Casey: Okay I do have a Robbie on the line, and they're going to further assist you with trying to find a cheaper alternative, okay?

[REDACTED]: Okay. Thank you for helping me.

Casey: Yes ma'am. Thank you for calling. You both have a wonderful day.

[REDACTED]: Okay, hold on. One more question. How long does it take to usually, once you put that order in, for me to get it? [crosstalk 00:02:05]

Casey: The [inaudible 00:02:07], it'll have to go through processing for two days and then it'll be shipped out to you.

[REDACTED]: Okay. Alright. Great, thank you.

Casey: You're welcome.

Robbie: Hello [REDACTED]. My name is Robbie. I'm gonna see what I can do to help you out today, okay?

[REDACTED]: Okay. Your name is Robbie?

Robbie: Yes ma'am.

[REDACTED]: Okay.

Robbie: Give me just a second while I access this file, okay?

[REDACTED]: Alright. Your voice is really low.

Robbie: Okay, well I'll try to speak louder.

[REDACTED]: Okay, Alrighty. My grandsons are watching cartoons so I turned that down some too.

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Robbie: Okay. I'm not really sure what's a alternative to this medication. I can reach out to the clinical department and see if there is a generic for it if you'd like me to do that.

Yeah. Now my doctor, doctor [inaudible 00:03:50], told me there was not a generic form, but I would appreciate you checking to because I can't afford \$350 a month for that medicine.

Robbie: Yeah. I'm not seeing anything that's comparable to this, but when I reach out to the clinical department we'll be speaking to a pharmacist, so they'll be able to give us some ideas, okay?

Okay.

Robbie: And I do apologize. I have to put you on a brief hold while I dial that number, and I need you to stay on the line in case they need to ask you some questions.

I will. I will.

Robbie: Okay.

Automated: You have reached CVS caremark clinical care services. If you have a retail pharmacist requesting a prescription transfer, press one.

Thank you for calling caremark prescription services. All of our customer service representatives are currently busy. Please hold for the next available representative.

All of our representatives are currently assisting other callers. Your call will be answered in the order that it was received.

Thank you for your patience. Please continue to hold and someone will assist you shortly.

Robbie: [redacted]?

Automated: Your command has been entered within the allowed period. You are now being returned to your caller.

Robbie: [redacted]?

Yes?

Automated: Thank you for your patience. Please continue to hold and someone will assist you shortly.

Robbie: I'm on hold, so give me just a second, okay?

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[REDACTED] Excuse me?

Robbie: I said I've been put on hold so give me just a second, okay?

[REDACTED] Okay. That's [inaudible 00:06:40].

Robbie: Okay.

Automated: Thank you for your patience. Please continue to hold and someone will assist you shortly.

Thank you for your patience. Please continue to hold and someone will assist you shortly.

Richard: This is Richard, pharmacy tech. May I help you?

Robbie: Hi. My name is Robbie and I'm calling from the Care Extension Review Team and I have a member on the line that needs to find a cheaper alternative.

Richard: You said your name is Ronnie?

Robbie: Robbie.

Richard: Oh Robbie, okay. You're breaking up a little so I couldn't hear you. Sorry.

Robbie: I apologize.

Richard: No that's alright. I know there's issues. What's the member's ID please?

Robbie: Uh-uh (negative). [REDACTED]

Richard: Thank you. Now verify the member's name and date of birth please.

Robbie: It's [REDACTED] and her date of birth is [REDACTED]

Richard: And is this for the Canasa.

Robbie: Yes sir. She said she can't afford the co-payment and I looked through all my references that I've got and I don't find anything.

Richard: Yeah.

Robbie: I mean it's on the formulary.

Richard: Go ahead and bring her on and I can help. Thank you.

[REDACTED]

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Robbie: Great. Thanks.

[REDACTED]

[REDACTED]: Yes?

Robbie: Hi. I can a pharmacy tech on the line and he's gonna be help to help you.

[REDACTED]: Okay.

Richard: Can you stay on the line Robbie just in case, please?

Robbie: Yes sir.

Richard: Thank you [inaudible 00:09:28]. Hello [REDACTED]. This is Richard, pharmacy technician here CVS and I was informed you called in regards to the Canasa suppositories.

[REDACTED]: Yes.

Richard: Okay, and let me ask you this. Are you able to take a tablet?

[REDACTED]: I guess. I mean I can take tablets. My doctor, [REDACTED], just gave me the [inaudible 00:09:55] years ago.

Richard: Okay. Give me one second.

[REDACTED]: Okay.

Richard: Let me try running a couple. I keep hearing some beeping noises.

[REDACTED]: Yeah, it's probably me. I'm sorry.

Richard: Oh, okay. Let's do [REDACTED]. We do a quick test thing for you real quick here. And do you get through mail service, or a local pharmacy, or...

[REDACTED]: No. I get it through Caremark mail order service.

Richard: Okay. Can I get you to run one please for me Robbie?

[REDACTED]: Now will a tablet be [inaudible 00:11:02] a suppository?

Richard: Give me one second [REDACTED], I'm gonna go ahead and run some test claims. Robbie, are you there?

Robbie: Oh I'm sorry. Yeah, I'm here Richard. I'm sorry.

[REDACTED]

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Richard: It's alright. Can you run one for me please?

Robbie: I sure can. Just spell it for me.

Richard: Actually I got a drug ID to put into the drug ID.

Robbie: That'd be great.

Richard: It's 68382071119 and just do for right now, just try to do I would say 270/490. Just to be on the safe side.

We're doing a test type for you [REDACTED] so just bear with us, okay?

[REDACTED] Okay. That's fine.

Richard: And then after we're done I'm gonna give you the name, but I'm gonna get a pharmacist to go over how this compares to...

[REDACTED] Yeah, and I was just wondering, maybe you can answer this question while she's running that. If it doesn't work and I have to do Canasa how would every other night work? Would it be oka that way ... I mean I can afford over \$1,000 every six months, I just can't afford it every three.

Richard: Yeah. That's something that, when I bring a pharmacist, they will be able to help you with that question as well ma'am. That was-

Robbie: Richard, I come up with a crazy co-pay. I come up with \$447?

[REDACTED] Yeah, no that's not gonna work. Well, my co-pay for Canasa's over \$1,000 for three months.

Richard: Yeah I see where it's for three months was \$951.72.

[REDACTED] The lady at Silversript told me it one 1,000 something.

Richard: Let me try running another one here. 874078, actually, let me just try running something else here for you. Let's see 278490, run the test. She ran the extended release.

[REDACTED] And I guess that's because of the prescription that [REDACTED] gave him for it.

Richard: What I'm gonna do is, yeah, just to make sure, I'm gonna reach out to a pharmacist and see if we have find something for you. Give me one second, okay?

[REDACTED] Thank you.

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Richard: Alright [REDACTED] and Robbie, I appreciate your patience in waiting. I do have a pharmacist on the line. Her name is Lauren and she's gonna help you with some alternatives. All three of you enjoy the rest of your day. Thank you.

[REDACTED] Thank you.

Lauren: Yes. Hello [REDACTED] and Robbie. Hi, this is Lauren and Richard tells me that you were calling today about the Canasa suppositories. That they're very expensive and so we're wanting to find a possible alternative that would be more affordable?

[REDACTED] Yes.

Lauren: Okay. Alright. Let's see here. Now, may I ask, what was the medication prescribed for?

[REDACTED] I had an inflamed colitis years ago, and [REDACTED] my GI, gastro doctor, that's what she prescribed, and she said I have to take one every night for the rest of my life.

Lauren: Oh, okay.

[REDACTED] And I thought, "Well, if there is no alternative, what would it do if I just took one every other night to make the prescription last six months?"

Lauren: Hmm. Yeah, see that I'm not sure other than I'm pretty sure that the symptoms would not be very well controlled. That's the only thing I can think of.

[REDACTED] [inaudible 00:18:13] since I've been taking Canasa I've never had any problems, but now I've been without it for over three weeks.

Lauren: Oh my goodness. Okay.

[REDACTED] Because my prescription ran out and the doctor couldn't get me in to examine me, or she didn't examine me, she listened to my breathing and felt my stomach and that was it. That was just Tuesday, so hush now, I'm on the phone. So, I've already been, like I said, I've been three weeks without it.

Lauren: Yeah. Okay. Let's see here. Okay, I'm just trying to see what other options that might be available for treatment of that. Let's see here.

[REDACTED] [REDACTED] says there are no other option.

Lauren: Oh, okay. Your doctor already said there aren't any other options?

[REDACTED] My doctor said there are no other options, but I asked the gentleman on the phone [inaudible 00:19:38] if he would check anyway, just to see.

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Lauren: Yeah. Yeah, there's another medicine that's called Hydrocortisone that comes in a couple of different dosage forms. I'm just trying to see though if it's okay for long term use, like you indicated. Let's see here. Yeah, because the Hydrocortisone is only recommended for up to three weeks at a time, and then to slowly discontinue it and then it would just be a cycle of using it, coming off of it, and then being off of it for a while. So, it's not as consistent of a treatment as the Canasa.

[REDACTED] Yeah.

Lauren: Yeah, and then it sounds like the oral medication wouldn't be an option either.

[REDACTED] Mm-hmm (affirmative).

Lauren: Let's see here. Let's see what other ... that one, no. It's not. Let's see here. Yeah, unfortunately I'm not seeing any appropriate alternatives either.

[REDACTED] Yeah.

Lauren: So, yeah sorry [crosstalk 00:21:12].

[REDACTED] Well, I'm gonna call my doctor back and see what she says about every other night or if she says maybe every third night or something like that, and instead of taking seven a night for a week, take five ... I mean not seven a night, but take them for seven straight nights, or maybe let's see what she'd say about five, because that makes my medicine over \$350 a month. I'm on Medicare.

Lauren: Yeah.

[REDACTED] I can't afford it.

Lauren: Yeah. Okay, yeah, I'm sorry about that, but yeah I guess that would be the next step. Yeah, see if the doctor can work out some alternate dosing with you. That might be the thing to do since-

[REDACTED] Yeah [inaudible 00:22:05]. Yeah she said there was no other alternative, but I just wanted to check to make sure. So now, I'll just call back because she said on the prescription that I'll have to pay 1,000 plus up front before they'll mail it to me.

Lauren: Oh god.

[REDACTED] So I need to try and see if I can't make this medicine last a little longer.

Lauren: Yeah, okay.

[REDACTED] Than every three months.

[REDACTED]

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Lauren: I see. Okay.

[REDACTED] I don't know how the expect people that's on Medicare and Social Security to be able to afford that. I don't know.

Lauren: Yeah. I see the price on it and it's very high so I'm not sure either. What I'm wondering though is customer care, Robbie, would the price go down at a certain point, or is it gonna be this high for the rest of the year.

Robbie: Let me see. She's in initial drug spend. I was looking into alternative medications. I don't even know, if we ask for a tier exception, if she could get it because there's nothing in that class to compare it to.

Lauren: Oh wow.

[REDACTED] Yeah, it's a tier four drug and they told me it was gonna be expensive and I told the doctor. They told me they could see if the doctor could prescribe something else. Well, she told me Tuesday night, she said there is no other alternative. What I think I'll do is just go back and see if I can skip a night once a week or once every three or four days or something.

Lauren: Yeah, okay.

Robbie: I don't know whether [inaudible 00:24:03] medication.

Lauren: No, it's been around for a few years.

Robbie: Okay.

Lauren: Yeah.

[REDACTED] Yeah I've been on it for, oh my lord, 10, 15 years, but when I was with United Healthcare I only had to pay \$150 every three months. Now I gotta pay over \$1,000 every three months.

Robbie: Yeah, because it's showing that the cost of this medication is \$3,970, so the plan is paying.

[REDACTED] Yeah. So, that's what Silverscripts is just gonna charge me a little over \$1,000 then. That's what you're telling me, right? Because it is a \$3,000 prescription.

Robbie: Yes ma'am.

[REDACTED] But the \$1,000 does cover three months, right?

[REDACTED]

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Robbie: Yes ma'am.

[REDACTED] Okay. Alright. Well, I'll talk to my doctor and then I'll call Silverscripts back and tell them to order it or whatever [REDACTED] says I have to do.

Robbie: Okay, well did you want me to run a test claim for just for thirty days?

[REDACTED] A test claim?

Robbie: Yeah it'll give us an average of what the co-pay would be.

[REDACTED] Okay.

Robbie: For thirty days?

[REDACTED] Yeah. [inaudible 00:25:32] for thirty days since I've been out this three weeks over. You just run it and tell me what it's gonna be.

Robbie: Yeah, it would just be an average. It's showing \$369.

[REDACTED] Yeah, no. No. I'd rather do the three months. I know it's cheaper with three months, a little bit cheaper so we'll just ... I'll call [REDACTED] and talk to her and then I'll call back Silverscripts and order whatever I decide to do. Because I know I have to take it because she said it could develop into cancer if I didn't take it. Is that correct?

Robbie: Yeah.

[REDACTED] Okay. Alrighty. Thank y'all for your help.

Robbie: Alright, well you have a great rest of your day.

[REDACTED] Thank you, you too. Bye.

Lauren: Take care. Bye, bye.

Robbie: Thank you.

[REDACTED] Bye, bye.

[REDACTED]
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EXHIBIT 70

Peoplesafe

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CAREMARK **PeopleSafe®** Close

Eligibility Maintenance **Participant Inquiry** Resolution Manager Medicare D Inquiry View Opportunities Tools: -- Select A Tool --

Client: **SILVERS, SCOTT - INDIV-ENROLL** System: RXCLAIM

External ID: **[REDACTED]** Name: **[REDACTED]** Gender: **F** Relationship: **MEMBER** Birth Date: **[REDACTED] 954** Effective: **03-01-2019** Expiration: **12-31-2039**

[Main Screen](#) [Financial Details](#) [View Activity](#) [Prescription History](#) [Test Claims](#) [Plan Benefit Override](#) [Account Balance](#) [Explanation of Benefits](#) [Transaction History](#) [Communication History](#) [Caremark.com](#)

[Pharmacy Network](#) [Retail Transaction](#) [Plan Summary](#) [FSA/HSA/HRA History](#) [Coordination of Benefits](#) [Order Placement](#) [Adjustments](#) [Client Managed \(G & A\)](#) [View Triggers](#)

Prescription for: **[REDACTED] MEMBER** Delivery System: **MAIL ORDER** Dispense As Written: **0 - NO DAW**
 Prescription Number: **[REDACTED]** Pharmacy NPI: **[REDACTED]** Drug Price Type: **AVERAGE WHOLESALE PRICE**
 Drug NDC: **58914050156** Pharmacy NCPDP: **[REDACTED]** Drug Price Source: **MEDISPAN**
 Drug Name: **CANASA** Pharmacy Name: **CAREMARK PRESCRIPTION SRVCS WEB** Client Claim Price Type:
 Pharmacy Claim Price Type:

Participant Pay Participant Copy: 1711.23 Initial Copy: 1711.23 Gap Copy: 0.00 Catastrophic Copy: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 1711.23	Client Pay Usual and Customary: Cost Submitted: 3978.74 Cost Allowed: 3492.32 Other Payer Recognized: 0.00 Dispensing Fee: 0.00 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 1781.09	Pharmacy Pay: Usual and Customary: Cost Allowed: 3492.32 Other Payer Recognized: 0.00 Dispensing Fee: 0.00 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 1781.09
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Health Reimbursement Account: Benefits: 0.00 Member Access Fee: Amount Used: 0.00 HRA Rollover Balance: 0.00	Miscellaneous Applied To Out of Pocket: 0.00 Applied To TROOP: 0.00 Applied To OOPM/MOOP: 0.00 Paid by Other Insurance: 0.00 Alternate Amount Paid: 0.00 Previous Amount Paid: 0.00 In Network Accumulation: 0.00 Out of Network Accumulation: 0.00
---	--

Med D Financials: LICs Paid by Plan: 0.00 SPAP/Integrator Paid Amt: 0.00 Reported Gap Discount: 0.00 Deductible Gross Cost: 0.00 Deductible Plan Pay: 0.00 Initial Gross Cost: 3492.32 Initial Plan Pay: 1781.09 Gap Gross Cost: 0.00 Gap Plan Pay: 0.00 Catastrophic Gross Cost: 0.00 Catastrophic Plan Pay: 0.00	View Settlement Codes View Comments Back
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EXHIBIT 71

This transcript was exported on Apr 23, 2019 - view latest version [here](#).

Speaker 1: Good afternoon. Thank you for calling customer care. Who am I speaking with today?

[REDACTED] Hi, my name is [REDACTED]

Speaker 1: And what can I assist you with?

[REDACTED] My doctor ... back on March 11th I had to have a colonoscopy, and she wanted me to have a medication, it's a Canasa suppository. And the expense, my copay would have been around \$800.

Speaker 1: Wow.

[REDACTED] The only thing that they can do that's different is one where you have to use an enema. I'm a paraplegic. I'm unable to do that myself. And so, at first, I just didn't get it filled because I couldn't afford it. Is there any exceptions that can be made, or anything else? I know I've got another medication where they changed the tier for it based on medical necessity.

Speaker 1: Yeah. What's the name of the medication?

[REDACTED] Canasa. She's doing a ... it's C-A-N-A-S-A. Canasa suppository.

Speaker 1: Okay. Let me take a look here.

[REDACTED] Thank you. And I need to ... the reason why I'm calling and asking you is, she had ordered the one, I did not pick it up, so she's going to reorder it again, and I ... so I'm calling you to find out. I don't want to mess up what was there on March 11th, and what she might be calling in today.

Speaker 1: I totally understand. Let's take a look here.

[REDACTED] Thanks.

Speaker 1: I'm just trying to see what was rejected on the 11th so I can go from there.

[REDACTED] Oh good, thank you.

Speaker 1: So they ... yeah, they were Mesalamine, is what it was. Let me see here. Okay. And it says dispense brand. Okay. Let me see what's going on. Bear with me here.

[REDACTED] Sure. No, I appreciate it.

Speaker 1: 'Cause if we can get you the brand at a tier two ... okay. Sorry, I'm just talking out loud. Bear with me.

[REDACTED]
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[REDACTED]: No, please. I appreciate anything you can do.

Speaker 1: Yeah, we'll see what we can do for you here. Oh, I forgot to look at the scrip. Is it one a day?

[REDACTED]: She had written down here, she said daily times eight weeks.

Speaker 1: Okay. And you're going to do these in the local pharmacy, correct?

[REDACTED]: Yeah. Walgreens, my primary. Or I can go wherever you need me to go. I can ... well she's going to send it over to Walgreens, which is my main pharmacy.

Speaker 1: Gotcha. Yeah, I'm showing the same thing. Please keep in mind, prices quoted are just estimates, may not reflect the actual out of pocket costs. It's showing 587.18 just for a 30 day supply. Let me see if I have anything alternative that is cheaper, okay?

[REDACTED]: Okay.

Speaker 1: Because I know it says to give the name brand, but if we're able to do the generic, that's gonna probably save you quite a bit, 'cause that's a tier two medication. Whereas the Canasa is a tier four, so you're paying a percentage where the tier two is an actual straight copay. So bear with me here. I'm trying to see what we can do for you.

[REDACTED]: Okay. The Canasa you said's a tier two?

Speaker 1: No, that's a tier four.

[REDACTED]: Oh, tier four. Okay.

Speaker 1: Yeah, that's why it's so high. Because you're paying a percentage of the medication. That was just for a 30 day supply that I quoted. Just trying to see if we can get you the Mesalamine instead.

[REDACTED]: Okay.

Speaker 1: Yeah, see the Mesalamine's ... it's still going to be kind of high. That's the thing. Yeah, it's still showing 453.82. Again, prices quoted are estimates, may not reflect actual out of pocket cost. If you don't mind, [REDACTED] I'm gonna put you on a brief hold. I want to speak to my clinical department. I want to speak to a pharmacist, see if there's anything we can do.

[REDACTED]: Thank you so much.

[REDACTED]
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Speaker 1: See if there's an alternative. And if there's not, then we can see if we can get your tier exception. Okay?

[REDACTED] I would appreciate it so much. Yeah, 'cause I'm a paraplegic, and I had a lot of medical things. So it would be helpful to me so much. [crosstalk 00:04:38].

Speaker 1: Absolutely. Alright, [REDACTED] I have your number as [REDACTED]. If for some reason we get disconnected, can I call you back at that number?

[REDACTED] Yeah. What's your name, by the way?

Speaker 1: [REDACTED]

[REDACTED] Okay, good name.

Speaker 1: Yeah. So the reason I say that is because if we get disconnected, you try to call back, you have to go through the whole automated system. You're going to get somebody else, have to repeat everything. I don't want you to have to go through that.

[REDACTED] I understand.

Speaker 1: So if for some reason we get disconnected, just give it a minute and let me call you back, okay? We probably won't, but just in case.

[REDACTED] Got it, thanks.

Speaker 1: So I'm gonna put you on a brief hold and bring them on the line, okay?

[REDACTED]: Great, thanks [REDACTED].

Speaker 1: You're welcome. I'll be right back, sir.

Speaker 1: ...

Speaker 1: All right, [REDACTED]

[REDACTED] I'm here.

Speaker 1: Thanks for holding. I apologize for the wait. I appreciate your patience. I'm still waiting on them to answer, but I wanted to at least touch back with you and let you know I'm still here, okay? May I put you back on a brief hold?

[REDACTED] Definitely, thanks.

Speaker 1: Thank you sir.

[REDACTED]
Transcript by [Rev.com](#)

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Speaker 1: ...

Speaker 1: All right, [REDACTED]?

[REDACTED]: I'm here.

Speaker 1: Hi. Thanks for holding again. I apologize for the wait. I appreciate your patience. Still waiting on pharmacy to pick up. And again, I apologize for the wait. I was doing a little research while I was waiting for them to answer. There's a discount program at Canasa.com where it says ... let me pull it back up here. It says there's a savings card that may help eligible patients pay as little as \$10 per prescription. Says it is valid for patients 18 and older, and good for use only with a valid prescription for the 1000 milligram suppositories. That's all I can see, because our sites are blocked. I could see like basically generic information. It's Canasa.com. That's if we can't find any alternative, but I wanted to let you know, I did find that. I'm not sure how to qualify or anything like that, and that'd be something to look at their website. But just trying to look at other options while I'm waiting for them to answer.

[REDACTED]: Okay, I'm going to look at it while I'm on hold. But yeah [crosstalk 00:12:08].

Speaker 1: Sure. So yeah, it's Canasa.com, and I think it says ... it says patient savings or something. I can't pull up the actual website because it's blocked for me. But it is up there. So yeah, if you want to look at that. And again, may I put you on a brief hold so I can speak to clinical?

[REDACTED]: Of course.

Speaker 1: Okay. Thank you.

Speaker 1: ...

Speaker 1: Hi, [REDACTED]?

[REDACTED]: I'm here, yeah.

Speaker 1: Thanks for holding. I apologize for the wait. Appreciate your patience. I'm still waiting on them to answer. They are quite busy. Again, I really apologize. I did find a few others too, if you wanted to look 'em up.

[REDACTED]: Yeah, the one you gave me, it's not eligible for Medicare, which is what I'm on, so ...

Speaker 1: Oh, no. Okay. Yeah, I didn't know.

[REDACTED]: That's okay.

[REDACTED]
Transcript by [Rev.com](#)

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Speaker 1: I know there's another one called PrescriptionHope.com. And of course, none of these, you're probably gonna be eligible through Medicare as well. You know what I mean? I don't know. But then there's the GoodRx.com. I don't know if you've heard of that.

[REDACTED]: So what are you saying, like doing it without insurance? Is that what you're ...

Speaker 1: Yeah. So this would be using it without Medicare, just to see if you're able to get it any cheaper. That's in case we have no alternatives, or in case we can't get a tier exception. I'm just trying to give you some alternatives.

[REDACTED]: Okay.

Speaker 1: It doesn't mean we can't still do those, but you know, while we're waiting, I just wanted ... if you wanted to look those up.

[REDACTED]: Sure, I'll take a look.

Speaker 1: And also, have you tried to apply for extra help through Social Security, to help pay your prescription costs?

[REDACTED]: Yeah. I've never had any luck at getting any.

Speaker 1: Okay.

[REDACTED]: Because I'm not on Medicaid, so I'd still ... I'm at that spot where I'm not bad enough, but, so ...

Speaker 1: Gotcha. Okay. That's horrible. Okay.

[REDACTED]: And being a paraplegic, I'm disabled too, but at the same time I still own my home, so I don't qualify for any of the ...

Speaker 1: Oh yeah, 'cause it's based on assets, and yeah, I got you. Understood. So yeah, try Prescription Hope and Good Rx if you don't mind. Real quick, I'm just gonna put you back on a brief hold, see if I can get them to answer, okay?

[REDACTED]: Okay.

Speaker 1: Thanks.

Speaker 1: ...

Speaker 1: Hi, [REDACTED]?

[REDACTED]: I'm here.

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Speaker 1: All right, thanks for holding. I apologize for the wait. I'm still waiting on our pharmacist to answer. Again, I'm so sorry for the wait. Their calls are backed up a little bit. So if you could be patient with me. I don't mind waiting if you do.

[REDACTED]: I appreciate your help, so go ahead.

Speaker 1: No problem. Perfect. Were you able to look at any of those other sites and see if there was anything?

[REDACTED]: I've got one, the Prescription Hope, I'm filling in ... I've got to sign up for it first, and then doing that. Sometimes it's stuff I've done before where I just end up on a ... I get a bunch of emails and promotions, but it doesn't really do anything. But I'm staying hopeful.

Speaker 1: Yeah, let's hope. Hopefully we can find an alternative that's cheaper, or at least get it covered under a different tier. So that's what we need to know first. And if not, at least you may have some alternative. But again, may I put you back on a brief hold to wait for them?

[REDACTED]: Sure, thanks [REDACTED]

Speaker 1: Thank you, [REDACTED]

Speaker 1: ...

Speaker 1: Hi, [REDACTED]?

[REDACTED]: Yeah, I'm here.

Speaker 1: Okay. Thanks for holding. I apologize for the wait, appreciate your patience, took awhile. So I got a pharmacy technician on the line. They looked, and they did not find any alternatives in the same class, okay? So you have the option of either, we can transfer it to an actual pharmacist itself, and see if they can find anything. Of course, reach out, back out to your doctor, or request a tier exception.

[REDACTED]: Okay. Yes, do I request a tier exception through you guys, or ...

Speaker 1: Through us, yes.

[REDACTED]: Yeah. Yeah, if I could do that, 'cause I tried that other one that you ... it would be \$50 a prescription, and there's no guarantee, and it takes six to eight weeks.

Speaker 1: Oh, wow.

[REDACTED]: I have to have this right now.

[REDACTED]
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Speaker 1: Right. Okay. So I think your best bet is probably ... like I said, a pharmacy tech couldn't find anything. So you want to just go ahead and do the tier exception?

[REDACTED]: Yeah. How long does it take to find out?

Speaker 1: Usually it only takes about a day or two. I have a dedicated team.

[REDACTED]: Great, let's do it.

Speaker 1: So let me put you on a brief hold. Let me go ahead and let the pharmacy tech go, okay?

[REDACTED]: Thanks [REDACTED]

Speaker 1: You're welcome. I'll be right back with you.

Speaker 1: ...

Speaker 1: All right, [REDACTED] Thanks for holding again. One moment, I'm gonna update everything on your account real quick, okay?

[REDACTED]: Okay, thank you.

Speaker 1: I apologize it took so long just to get an answer that we didn't like. But at least they had to look. It probably did ... just took a little while.

[REDACTED]: Yeah. Who decides on the tier exception? How does that work?

Speaker 1: So what they do is they just ask you some information, they send the information over to your physician, your physician answers it, and they send it back. They're going to ask a diagnosis, and why you need it, things like that. Let 'em know the reason, you need the medication but the cost is too high, and then it's just determined from there. The quicker your doctor can reply to it, the quicker we can get it approved.

[REDACTED]: Okay.

Speaker 1: Okay. So once we do this and send it over, probably be a good idea ... probably a little late today ... Oh actually, no. You're only at 3:00 there. So if they're able to get it over to your doctor today, and if he can reply today, that's going to be quicker. If not, he'll probably get it ... or, he or she will get it first thing in the morning.

[REDACTED]: Okay. They'll send it to the doctor's office, or ...

[REDACTED]
Transcript by [Rev.com](#)

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Speaker 1: I'm sorry. Yeah, yeah. They're going to reach out to the doctor's office and send that information over. However, I have a dedicated team I have to transfer you to. But I'm going to let them know that what you're asking for is a tier exception request for the Canasa, okay? So when they receive the call, they're gonna know exactly what it's about. They're going to say, okay ... they're going to ask the same thing. Do you want any alternatives? That's when you say, "Look, I just spoke to [REDACTED] we spoke to clinical," they'll see all the notes. "There is no alternatives. This is the medicine I need as soon as possible," okay?

[REDACTED]: Okay, thanks [REDACTED]

Speaker 1: Yeah, no problem. And again, I apologize it took so long. Let me put all these notes in here so when they get the call, they already know what's going on, okay? So you don't have to try to re ... they may question a little bit here and there, and ask you about alternatives. But you can let 'em know, if you review the notes, we've already did that, okay? That eliminates that step. Because they're going to do the same thing. They're going to try to find you something. But if you let them know we already did it, then it's going to just be quicker for you, okay?

[REDACTED]: Okay, thanks.

Speaker 1: All right. And before I get that over there, [REDACTED] to the tier exception review team for the Canasa tier exception requests, is there anything else I can assist you with today?

[REDACTED]: No. That's all I need.

Speaker 1: Okay.

[REDACTED]: Thanks.

Speaker 1: You're welcome. Give me just one moment here. And I'm going to get you right over. You enjoy the rest of your day, it was good talking with you, and thanks for calling today, okay?

[REDACTED]: Thanks. Thanks [REDACTED]

Speaker 1: You're welcome, sir. Here we go. I'm gonna go ahead and transfer you right now.

[REDACTED]: Okay.

EXHIBIT 72

Peoplesafe

Signatory Maintenance | Participants Inquiry | Transaction History | Medicare D Inquiry | [View Opportunities](#) | Tools: -- Select A Tool --

Client: [REDACTED] SILVERSCRIPT-INDIV ENROLL System: RXCLAIM

External ID: [REDACTED] Name: [REDACTED] Gender: M Relationship: MEMBER Born: [REDACTED] 957 Effective: 01-01-2017 Expiration: 12-31-2039

Health Coverage: [REDACTED] View Activity: [REDACTED] Prescription History: [REDACTED] Test Claim: [REDACTED] Plan Details: [REDACTED] Account Balance: [REDACTED] Explanation of Benefits: [REDACTED] Transaction History: [REDACTED] Communication History: [REDACTED] Caremark.com: [REDACTED]

Pharmacy Network: [REDACTED] Retail Transaction: [REDACTED] Plan Summary: [REDACTED] PSA/HSA/HRA History: [REDACTED] Contributions of Benefits: [REDACTED] Drug Placement: [REDACTED] Acquaintance: [REDACTED] Claim Managed G.I.A.: [REDACTED] View Triggers: [REDACTED]

Prescription for: [REDACTED] **CLAIM INFORMATION ONLY**

Origin: 3 - Electronic Received: 03-21-2019 Kit Type: [REDACTED]
 Number-Partial / Fill: [REDACTED] Filled: 03-21-2019 Kit Copy Bypass: [REDACTED]
 Claim / Sequence: [REDACTED] Controlled Substance: NOT APPLICABLE Compound: N - NO
 Override Type/Id: [REDACTED] Status: Paid 03-21-2019 06:18:05 PM
 Multiple PA's: [REDACTED]

Drug

Dispensed Drug: CANASA-1000MG Prescribed Quantity: [REDACTED] Unit Per Dose: [REDACTED]
 Dispensed ID: [REDACTED] Dispensed Day Supply: 30 Dose Per Day: [REDACTED]
 Prescriber Name: [REDACTED] Dispensed Quantity: 30.000 Drug Type: BRAND
 Pharmacy Name: CVS PHARMACY [REDACTED] Covered Day Supply: [REDACTED] Dispense as Written: 1 - PHYSICIAN DAW
 Ingredient Name: [REDACTED] Covered Quantity: [REDACTED] GPI: 52500030005240
 Formulary Preference: Non Preferred Formulary Tier: 4

Reject Codes	Reject Description	Settlement Codes	Settlement Description
10500	DISCUSS ONRHC SAVINGS OPPORTUNITY W/MBR COB DATA FROM MEDICIN LINKAGE TABLE		

General [Show](#)

Medicare Part D [Show](#)

View Financials | View Comments | View Transmission | View Drug Limitations | Populate Test Claim | Available Overrides

EXHIBIT 73

Template Instructions:

Use the "Find and Replace" function to replace the following variable fields in the document with the applicable values:

Variable Field Name	Description	Example(s)	Number of Replacements
ADVAIR DISKUS	Brand name of drug, all caps	ESTRACE, ISTALOL	5
INHALATION AEROSOL POWDER BREATH ACTIVATED	Strength and dosage form, all caps	1% GEL	4
ADVAIR DISKUS	Brand name of the drug to include strength (if applicable) and dosage form, all caps	ESTRACE 0.1% CREAM	33
<DOCUMENT_NUMBER>	Document name/number specific to the script; assigned by CARE	Y0080_72110_SCR_2018	1
<TREATMENT>	Description of the common use(s) for the drug	For ISTALOL: elevated pressure in the eye	1
fluticasone-salmeterol aerosol powder breath activated	Generic of the drug to include strength (if applicable) and dosage form, all lowercase	timolol maleate 0.5% ophthalmic solution	17
using	How the member is utilizing the drug. "using" is more appropriate for topical or inhalation		5

	applications, "taking" for oral		
Preferred Brand Tier		Preferred Generic Tier, Generic Tier, Preferred Brand Tier, Preferred Brand Tier, Specialty Tier	11
Tier 3		Tier 1, 2, or 3	15

MED D - ADVAIR DISKUS® INHALATION AEROSOL POWDER BREATH ACTIVATED Generic Not Available for SilverScript Choice, Plus, and Allure (PDP) Plans Until Further Notice <Document_Number>

[Overview](#)

[Background](#)

[Rationale](#)

[What does this mean for the beneficiary?](#)

[Effects of this Strategy on Beneficiaries](#)

[FAQs](#)

[Log Activity](#)




[Resolution Time](#)

[Parent SOP](#)

Grievance Standard Verbiage:

Grievance Standard Verbiage (for use in Discussion with Beneficiary) section in [MED D Care - Grievances in PeopleSafe and MedHOK](#)

Legend:

Icon	Explanation
	Updates to information. The icon should be followed by the date of update. Note: Only the last update will be identified.
	Indicates Important or Urgent information
	Indicates a Talk Track

Overview

ADVAIR DISKUS® INHALATION AEROSOL POWDER BREATH ACTIVATED is a branded prescription drug commonly used for the treatment of <TREATMENT>. This prescription drug was recently launched in its generic form, fluticasone-salmeterol aerosol powder breath activated . The generic form of ADVAIR DISKUS is not available on SilverScript Choice, Plus, or Allure (PDP) plans until further notice.

ADVAIR DISKUS will be MAINTAINED on the Preferred Brand Tier (Tier Tier 3) in 2019 on the formularies for SilverScript Choice, Plus, and Allure beneficiaries. The generic, fluticasone-salmeterol aerosol powder breath activated , will **NOT** be added to the formularies.

This applies only to SilverScript Choice, Plus, and Allure beneficiaries in 2019.

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Background

Generic prescription drugs are typically the lowest-cost option when compared to branded prescription drugs. SilverScript **promotes the use of generic prescription drugs** to help plan beneficiaries save money.

- During the initial launch phase for the generic, there will be few manufacturers marketing the generic and the cost of the generic is expected to be relatively high.
- To help keep out-of-pocket costs low, SilverScript is retaining brand ADVAIR DISKUS® INHALATION AEROSOL POWDER BREATH ACTIVATED on its formulary on Preferred Brand Tier (Tier Tier 3). ADVAIR DISKUS is eligible for a manufacturer discount in the coverage gap.
- SilverScript will continue to keep the brand version of ADVAIR DISKUS on the formulary and will **NOT** be adding the generic version until further notice.

Network Pharmacies were also informed of this update.

NOTE: SilverScript Employer PDP Plans are being handled differently.

- **SilverScript Choice, Plus, and Allure Plans**

The generic version of ADVAIR DISKUS (fluticasone-salmeterol aerosol powder breath activated) will **NOT** be added to the SilverScript formularies for SilverScript Choice, Plus, and Allure plans in 2019.

- **SilverScript Employer PDP Plans**

Employer PDP Plans have added the generic (fluticasone-salmeterol aerosol powder breath activated) to their formulary for 2019. Some plans will continue cover the brand in 2019.

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Rationale

The goal of this document is to prepare the MED D Customer Care Representative (CCR) for potential inbound questions from the beneficiary regarding the availability of fluticasone-salmeterol aerosol powder breath activated and the non-covered status for this prescription drug on SilverScript Plans.

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What does this mean for the beneficiary?

Retaining brand ADVAIR DISKUS on Preferred Brand Tier (Tier Tier 3) can help keep out-of-pocket costs low for SilverScript beneficiaries.

NOTE: The generic equivalent fluticasone-salmeterol aerosol powder breath activated is **NOT** be on the formulary until further notice.

- Beneficiaries have the option to request an exception if they wish to obtain fluticasone-salmeterol aerosol powder breath activated .
 - However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.

- Brand ADVAIR DISKUS is available at the Preferred Brand Tier (Tier Tier 3) copay/coinsurance, so if the request for the generic is granted, the beneficiary would pay the amount associated with the plan's exception tier. This may be a different cost than the brand.

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Effects of this Strategy on Beneficiaries

- Beneficiaries will continue to receive the brand ADVAIR DISKUS at the Preferred Brand Tier (Tier Tier 3) cost share.
- The CCR may receive calls from MED D beneficiaries who are confused about the lack of generic version availability of the prescription drug. Refer to the [FAQs](#) section of this document for appropriate responses.

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FAQs

The frequently asked questions below will assist the CCR when addressing incoming calls regarding ADVAIR DISKUS.


NOTE: These specifics apply to non-LIS beneficiaries. See specific Q&A at end of this FAQ section for information specific to LIS beneficiaries.

Question	Answer	
Will ADVAIR DISKUS cost more than fluticasone-salmeterol aerosol powder breath activated in any stage of the Medicare D benefit for non-LIS beneficiaries?	SAY: <ul style="list-style-type: none">This will vary based on your Plan and which Medicare Part D coverage stage you currently are in (e.g., Deductible, Initial Coverage Limits, Coverage Gap or Catastrophic). CCR Process Note: The CCR will review the following grid for information on the anticipated costs of ADVAIR DISKUS vs. fluticasone-salmeterol aerosol powder breath activated during the fluticasone-salmeterol aerosol powder breath activated initial launch period:	
	Deductible Stage for non-LIS beneficiaries:	SilverScript Choice , Plus, and Allure beneficiaries: <ul style="list-style-type: none">In 2019, no deductible except for Choice Plan beneficiaries who will have a \$100 annual deductible for drugs in Tiers 3 to 5 for beneficiaries residing in Colorado, Georgia, or Texas; Choice beneficiaries residing in Arizona, South Carolina, or Alaska will have a \$Tier 315 deductible for drugs in Tiers 3 to 5. SilverScript Plus and Allure Plans are not available in Alaska. Move to response below in Initial Coverage Limits Stage.
	Initial Coverage Limits (ICL) Stage for non-LIS beneficiaries:	SAY: <ul style="list-style-type: none">Maybe.You will continue to pay your current Preferred Brand Tier (Tier Tier 3) cost share during the Initial Coverage Limits stage for brand ADVAIR

		<p>DISKUS.</p> <ul style="list-style-type: none"> Mr. /Mrs. <Beneficiary>, your cost share for brand ADVAIR DISKUS will be <\$X.XX>. <p>Move to response below in Coverage Gap Stage.</p>
	Coverage Gap Stage for non-LIS beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> No. The Coverage Gap Stage (also called the donut hole) is where you will receive significant savings on brand ADVAIR DISKUS. The brand name is less expensive than the generic version because of the manufacturer discount on brand name prescription drugs. In 2019, your cost share in the Coverage Gap Stage is 25% of the price of brand ADVAIR DISKUS. If the generic were included at this time on the formulary, your cost share would be 37%. <p>Move to response below in Catastrophic Coverage Stage.</p>
	Catastrophic Stage for non-LIS beneficiaries:	<p>SAY:</p> <ul style="list-style-type: none"> Yes. During this stage of the benefit, it is expected that - because of the price of the brand and generic versions - you will pay 5% of the allowed cost.
Why is the brand-name	SAY:	

ADVAIR DISKUS on the formulary when there is now a generic available?	<ul style="list-style-type: none"> • In this case, the price of the generic version of ADVAIR DISKUS will likely be similar to the price of the brand version for a minimum of six months, and perhaps longer. • There are few manufacturers of the generic version of ADVAIR DISKUS to drive the price down. • Until there are competitors and the price of the generic version goes down, your plan will continue to cover brand-name ADVAIR DISKUS at the Preferred Brand Tier (Tier Tier 3) cost share in 2019.
Why can't I get the generic? Aren't generics less expensive?	<p>SAY:</p> <ul style="list-style-type: none"> • When a generic version is first available, it is typically similar in price to the brand version. • At this time the generic version, called fluticasone-salmeterol aerosol powder breath activated , is not on the formulary. <ul style="list-style-type: none"> ◦ You do have the option to request a formulary exception. ◦ However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.
Will my other copays for other prescription drugs be lowered?	<p>SAY:</p> <ul style="list-style-type: none"> • No. • You will continue to pay the copay/coinsurance for other brand name and generic prescription drugs at the current benefit cost share.
Could there be other brand prescription drugs that this applies to?	<p>SAY:</p> <ul style="list-style-type: none"> • In most cases the generic version of a prescription drug is less expensive than the brand name version and is covered at the lower generic copay. • The exception typically applies during the first few years the generic version of a prescription drug is launched.
How long will ADVAIR DISKUS remain on the	<p>SAY:</p> <ul style="list-style-type: none"> • We anticipate that ADVAIR DISKUS will remain on the formulary on the

formulary on the Preferred Brand Tier (Tier Tier 3)?	<p>Preferred Brand Tier (Tier Tier 3) in 2019 until the price of the generic form of ADVAIR DISKUS drops.</p> <ul style="list-style-type: none"> • We anticipate it will be a minimum of six months, however that is based on market conditions not within our control and could change.
What should I do if brand ADVAIR DISKUS is removed from the formulary during the plan year?	<p>SAY:</p> <ul style="list-style-type: none"> • We will provide you with notification if brand ADVAIR DISKUS is removed from the formulary during the Plan year. • The type of notification depends on whether you are using the prescription drug and whether the change happens during the plan year or at the beginning of the next plan year. <ul style="list-style-type: none"> ◦ If we make this change during the plan year, and you are using ADVAIR DISKUS, you will receive written notification of the change in your Explanation of Benefits (EOB). ◦ If we make this change at the beginning of the next plan year, the change will be noted in the formulary included as part of your Annual Notice of Change (ANOC) packet. ◦ You should review your plan's formulary carefully. • If brand ADVAIR DISKUS is removed from the formulary and you want to continue using brand ADVAIR DISKUS, you will have the option to request a formulary exception. • However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.
May I, as the beneficiary, request a coverage determination for the generic product?	<p>SAY:</p> <ul style="list-style-type: none"> • Yes, you as the beneficiary may request a coverage determination for fluticasone-salmeterol aerosol powder breath activated . <ul style="list-style-type: none"> ◦ However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.

	 Refer to the Med D Care - Coverage Determination/Appeal (New or Status Update) document.	
Will fluticasone-salmeterol aerosol powder breath activated be added to the formulary during the 2019 plan year?	SAY: <ul style="list-style-type: none"> The addition of the generic to the formulary will be re-evaluated during the year. 	
Will ADVAIR DISKUS cost more than fluticasone-salmeterol aerosol powder breath activated in any stage of the Medicare Part D benefit for LIS beneficiaries?	CCR Process Note: The CCR will review the following information for LIS beneficiaries on the anticipated costs of ADVAIR DISKUS vs. fluticasone-salmeterol aerosol powder breath activated during the fluticasone-salmeterol aerosol powder breath activated initial launch period:	
	For LIS 1 & 2 Beneficiaries:	SAY: <ul style="list-style-type: none"> Maybe. In the Catastrophic Coverage Stage of the benefit, you will continue to receive ADVAIR DISKUS at no cost. If you have not yet reached the Catastrophic Coverage Stage, you might have to pay your brand name copayment for ADVAIR DISKUS until you reach the Catastrophic Coverage Stage.
	For LIS 3 Beneficiaries:	SAY: <ul style="list-style-type: none"> No.
	For LIS Tier 3 Beneficiaries:	SAY: <ul style="list-style-type: none"> Maybe. If you are in the Initial Coverage Limits Stage (ICL) or the Post-Initial Coverage Limits Stage

		<p>of the benefit you will continue to pay your current coinsurance for ADVAIR DISKUS.</p> <ul style="list-style-type: none"> If you are in the Catastrophic Coverage Stage, you will continue to pay the LIS brand name copayment for ADVAIR DISKUS.
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[Top of the Document](#)**Log Activity**

1003 – Plan Design Education

[Top of the Document](#)**Resolution Time**

Information = immediate

[Top of the Document](#)**Parent SOP**

CALL-00Tier 38: [Medicare Part D Customer Care Call Center Requirements- CVS Caremark Part D Services, L.L.C.](#)

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EXHIBIT 74

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Kandace Thomas : Thank you for calling Customer Care. My name is Candace. Can I have the member's first and last name?

Beneficiary 15: [REDACTED].

Kandace Thomas : Okay, spell your first name for me.

Beneficiary 15: [REDACTED].

Kandace Thomas : All right. And what is your date of birth?

Beneficiary 15: [REDACTED].

Kandace Thomas : Okay. And Ms. George, can you give me your zip code?

Beneficiary 15: [REDACTED].

Kandace Thomas : Perfect. And just one of the medications that you take.

Beneficiary 15: Advair Diskus.

Kandace Thomas : All right. Perfect. And thank you so much for that. How can I assist you today?

Beneficiary 15: Pardon?

Kandace Thomas : How can I assist you today?

Beneficiary 15: Okay. I went to get my Advair Diskus, and I know that there's a generic available and it seems like SilverScript is not covering the generic and because it's not on the formulary and that is wrong. And I would like the Wixela.

Kandace Thomas : Okay. So you would prefer the generic?

Beneficiary 15: Yes. The pharmacy is supposed to offer me the generic versus the preferred brand and the SilverScript should not have anything to do with my preference with, especially when there's a generic available.

Beneficiary 15: Right. Okay. Well-

Beneficiary 15: And another thing is the cost probably will be cheaper and I won't go in the donut hole maybe.

Kandace Thomas : Okay. Well, in this case, let's see. This brand, yeah so the generic is not on the formulary. And so I'm looking at it now and I do see here that the generic is not on the formulary. So in this case, the brand is preferred. In some cases they prefer the generics, but in this case, the brand is preferred. So are you wanting to see about trying to get the generic?

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Beneficiary 15: Yes. Yes.

Kandace Thomas : Okay. So let's see. Okay. All right. So that would require, so what'll have to happen is called a formulary exception since this one is not on the formulary. We'll have to start the process to try and get this particular one on the formulary in your case. Okay. So that means I have to get our Care Exception Review Team on the line. They'll speak with you, and then they'll get our Coverage Determination Team. And they'll let you know the steps from there. Okay?

Beneficiary 15: Okay.

Kandace Thomas : All right. So bear with me one moment here and let me get them on the line.

Beneficiary 15: Who will I be speaking with?

Kandace Thomas : I'm going to get our Care Exception Review Team on the line.

Beneficiary 15: Our what? It's hard to understand you for some reason.

Kandace Thomas : Okay. I do apologize. It's called the Care Exception Review Team.

Beneficiary 15: Care reception Review Team.

Kandace Thomas : Yes, ma'am.

Beneficiary 15: Something like that.

Kandace Thomas : Except, uh-huh (affirmative), yeah. They're going to offer alternatives, that is their stage in the process. And if you just want this particular one, then at that point, they'll get our Coverage Determination Team. Okay.

Beneficiary 15: Okay.

Kandace Thomas : All right. So bear with me one moment. Let me get them on the line for you.

Beneficiary 15: Okay.

Kandace Thomas : All right. [REDACTED] ?

Beneficiary 15: Yeah.

Kandace Thomas : Yes. So I got the Care Exception Review Team on the line. And when I explained to them what was going on, you were wanting to get the Wixela covered, she had let me know that in cases where the note says dispense brand, you have to get the brand. She said there's no way you can get a formulary exception on that, because it's specifically saying. She said normally when they say that, that

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means there's something going on with the generic. So they prefer the brand. And actually now that I'm doing it, that Wixela is way more expensive than the Advair. The Wixela is almost \$200.

Beneficiary 15: \$200 for whom?

Kandace Thomas : For the Wixela, the generic.

Beneficiary 15: I pay \$38 for Advair myself through SilverScript.

Kandace Thomas : Right.

Beneficiary 15: The plan paid \$359.48.

Kandace Thomas : Yes ma'am.

Beneficiary 15: What are you telling me?

Kandace Thomas : What I'm telling you is that the Wixela, if you were to get that one... you can't get an exception on it. But the only good thing with that is that if you were to pay for the Wixela, you're going to be paying \$128 for it. The brand is actually cheaper.

Beneficiary 15: I know somebody that gets it and they don't pay that.

Kandace Thomas : Well, they-

Beneficiary 15: Well, it sounds like SilverScript just doesn't want to change because it's to their benefit and I'm not feeling that they're thinking of the consumer and it's hard for me to believe that the generic is pricier than the Advair.

Kandace Thomas : Yes, ma'am.

Beneficiary 15: It shouldn't be that way. Well, maybe according to SilverScript, because they want it to be. So there is no exception, right? Is that what you're telling me?

Kandace Thomas : That is what I was told by our Care Exception Review member. When it says to dispense the brand, normally in cases when it says specifically dispense the brand, that means we're giving you the brand instead of the generic because something is going on with that generic. And that's actually looking-

Beneficiary 15: What?

Kandace Thomas : If I knew, I promise I would tell you. I really don't know that it's just what she said, but it has a specific note. And even when they pulled it up at the pharmacy, it literally says dispense brand. So if there's something going on

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where we don't want to give it to you, where it may affect you, then we're not going to. We don't want you to receive anything that's not-

Beneficiary 15: Well, I will talk with my doctor about this and I will find out other things and-

Kandace Thomas : Okay.

Beneficiary 15: If I don't like what SilverScript is doing, I won't have script in the future. So I will find out on my own what the scoop is. But I don't like personally what SilverScript is doing.

Kandace Thomas : Okay. Now if you're wanting to talk to somebody and maybe see if they can do the exception, I was just told-

Beneficiary 15: But you just told me that there are no exceptions.

Kandace Thomas : That is what I just told you, but what I'm asking you now, well... There's no. Okay.

Beneficiary 15: Pardon?

Kandace Thomas : No, you're right. There's no exception on that. So was there anything else I could assist you with today other than discussing that Advair and that Wixela?

Beneficiary 15: No, not right now.

Kandace Thomas : Perfect. Well, thank you so much for calling and you enjoy the rest of your day.

EXHIBIT 75

This transcript was exported on Jan 24, 2022 - view latest version [here](#).

Recording: You have reached the CD specialized team. Please hold for the next representative. Your call may be monitored or recorded to ensure quality.

Kiana: Thank you for calling the care center review team. My name is Kiana. Can I have your first name, last initial?

Kandace Thomas: Candace T., like Tom.

Kiana: All right. What's your ZID?

Kandace Thomas: My ZID is 260714.

Kiana: Site location?

Kandace Thomas: Jonesboro.

Kiana: Who is the supervisor?

Kandace Thomas: Thomas B., like boy.

Kiana: What is the members ID?

Kandace Thomas: That is [REDACTED].

Kiana: Members name, date of birth, and client code?

Kandace Thomas: [REDACTED].

Kiana: Do you need a code for the member for the authenticate?

Kandace Thomas: Yes.

Kiana: Okay. What's the reason for the call?

Kandace Thomas: She was trying to get her WIXELA INHUB filled, but she was told at the pharmacy that she had to use the brand name, which ADVAIR DISKUS. She's really upset about that. She wants to use the generic. She's wanting to get an exception on that one.

Kiana: She can not use that medication. She has to use the brand. That's why it's saying dispense her to brand.

Kandace Thomas: She was saying it's wrong, and you can't tell me what to buy. She absolutely cannot get an exception on that WIXELA?

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Kiana: No. That one, that medication, anytime they say dispense brand, it's something going on with that medication. We have to dispense her the brand. Her doctor actually wrote her a prescription for the brand. We have to give her.

Kandace Thomas: Right. She knows that she was wrote that prescription. She is wanting it... I'll just let her know that she has to get that one.

Kiana: Right. If she was to get that medication, it's going to be higher than the one she has, it's almost \$100.00. That medication, she has to be dispensed the brand. That's what she has to have.

Kandace Thomas: Okay. All right. Sounds good. Thank you so much.

Kiana: You're welcome. Anything else I can assist you with today?

Kandace Thomas: No, that's it.

Kiana: All right. Thank you. Have a good day.

Kandace Thomas: You, too.

EXHIBIT 76

Peoplesafe

Page 1 of 1

CAREMARK **PeopleSafe®** Close

Eligibility Maintenance ☐ Participant Inquiry ☐ Resolution Manager ☐ Medicare D Inquiry ☐ View Opportunities Tools: -- Select A Tool --

Client: **SILVERSCRIPT-INDIV-ENROLL** System: **RXCLAIM**

External ID: **[REDACTED]** Name: **[REDACTED]** Gndr: **F** Relationship: **MEMBER** Born: **[REDACTED] 941** Effective: **04-01-2018** Expiration: **12-31-2039**

[Main Screen](#) [Financial Details](#) [View Activity](#) [Prescription History](#) [Test Claims](#) [Plan Benefit Overview](#) [Account Balance](#) [Explanation of Benefits](#) [Transaction History](#) [Communication History](#) [Caremark.com](#)

[Pharmacy Network](#) [Retail Transaction](#) [Plan Summary](#) [FSA/HSA/HRA History](#) [Coordination of Benefits](#) [Order Placement](#) [Adjustments](#) [Client Managed G & A](#) [View Triggers](#)

Prescription for: **[REDACTED] MEMBER** Delivery System: **POINT OF SALE** Dispense As Written: **9 - PLAN REQ BRAND**
 Prescription Number: **[REDACTED]** [Go to Reimbursement...](#) Pharmacy NPI: **[REDACTED]** Drug Price Type: **AVERAGE WHOLESALE PRICE**
 Drug NDC: **173069600** Pharmacy NCPDP: **[REDACTED]** Drug Price Source: **MEDISPAN**
 Drug Name: **ADVIAIR DISKUS** Pharmacy Name: **CVS PHARMACY [REDACTED]** Client Claim Price Type: **[REDACTED]** Pharmacy Claim Price Type: **[REDACTED]**

Participant Pay Participant Copay: 38.00 Initial Copay: 38.00 Gap Copay: 0.00 Catastrophic Copay: 0.00 Network Penalty: 0.00 Deductible: 0.00 MAC / DAW Penalty: 0.00 Non Formulary Penalty: 0.00 After MAB: 0.00 - FSA Contribution Amount: 0.00 - HRA Contribution Amount: 0.00 + COB Non Covered Amt: 0.00 ===== Participant Cost: 38.00	Client Pay Usual and Customary: 472.72 Cost Submitted: 472.72 Cost Allowed: 397.08 Other Payer Recognized: 0.00 Dispensing Fee: 0.40 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PRX Fee Amount: 0.00 Client Billed Cost: 0.00 Total Client Cost: 359.48	Pharmacy Pay: Usual and Customary: 397.08 Cost Allowed: 397.08 Other Payer Recognized: 0.00 Dispensing Fee: 0.40 Level Of Effort Fee: 0.00 Administration Fee: 0.00 Performance / Service Fee: 0.00 Sales Tax: 0.00 PDP Service Fee: 0.00 Other Amount Paid: 0.00 Total Pharmacy Reimbursement: 359.48
--	--	--

Health Reimbursement Account:
 Benefits: 0.00
 Member Access Fee: 0.00
 Amount Used: 0.00
 HRA Remaining Balance: 0.00
 Capture Activity

Med D Financials:
 LICs Paid by Plan: 0.00
 SPAP/Integrator Paid Amt: 0.00
 Reported Gap Discount: 0.00
 Deductible Gross Cost: 0.00
 Deductible Plan Pay: 0.00
 Initial Gross Cost: 397.48
 Initial Plan Pay: 359.48
 Gap Gross Cost: 0.00
 Gap Plan Pay: 0.00
 Catastrophic Gross Cost: 0.00
 Catastrophic Plan Pay: 0.00

Miscellaneous
 Applied To Out of Pocket: 0.00
 Applied To TROOP: 0.00
 Applied To OOPM/MOOP: 0.00
 Paid by Other Insurance: 0.00
 Alternate Amount Paid: 0.00
 Previous Amount Paid: 0.00
 In Network Accumulation: 0.00
 Out of Network Accumulation: 0.00

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Pharmacy Reimbursement

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

Reversal

Reimbursement Type:
 Reimbursement Number:
 Reimbursement Amount:
 Posting Date:
 Reporting Number:

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Recipient

Name:
 Alternate Name:
 Address:
 City:
 State:
 Zip:

[Go to top](#)

EXHIBIT 77

2019.02.27 Advair Diskus Gx Rejected Claims

<u>Date of Service</u> (Fill Date)	<u>RxClaim Claim #</u>	<u>Drug Label Name</u>	<u>Claim Status</u>	<u>Local Msg</u> (Custom Message)
02/27/2019	190644495902010	FLUTIC/SALME AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644495940010	FLUTIC/SALME AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644495948010	FLUTIC/SALME AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644495964010	FLUTIC/SALME AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644495970010	FLUTIC/SALME AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644495987010	FLUTIC/SALME AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644495993010	FLUTIC/SALME AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496009010	FLUTIC/SALME AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496015010	FLUTIC/SALME AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496032010	FLUTIC/SALME AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496038010	FLUTIC/SALME AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496054010	FLUTIC/SALME AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496061010	FLUTIC/SALME AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496077010	FLUTIC/SALME AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496084010	FLUTIC/SALME AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496100010	FLUTIC/SALME AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496106010	FLUTIC/SALME AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496122010	FLUTIC/SALME AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496129010	FLUTIC/SALME AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496145010	FLUTIC/SALME AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS

<u>Date of Service</u> <u>(Fill Date)</u>	<u>RxClaim Claim #</u>	<u>Drug Label Name</u>	<u>Claim Status</u>	<u>Local Msg</u> <u>(Custom Message)</u>
02/27/2019	190644496151010	FLUTIC/SALME AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496168010	FLUTIC/SALME AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496174010	FLUTIC/SALME AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496190010	FLUTIC/SALME AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496196010	FLUTIC/SALME AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496212010	FLUTIC/SALME AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496219010	FLUTIC/SALME AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496234010	FLUTIC/SALME AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496241010	FLUTIC/SALME AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496257010	FLUTIC/SALME AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496263010	FLUTIC/SALME AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496280010	FLUTIC/SALME AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496286010	FLUTIC/SALME AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496302010	FLUTIC/SALME AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496308010	FLUTIC/SALME AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496323010	FLUTIC/SALME AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496330010	WIXELA INHUB AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496345010	WIXELA INHUB AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496351010	WIXELA INHUB AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496367010	WIXELA INHUB AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496373010	WIXELA INHUB AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496389010	WIXELA INHUB AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS

<u>Date of Service</u> <u>(Fill Date)</u>	<u>RxClaim Claim #</u>	<u>Drug Label Name</u>	<u>Claim Status</u>	<u>Local Msg</u> <u>(Custom Message)</u>
02/27/2019	190644496395010	WIXELA INHUB AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496411010	WIXELA INHUB AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496417010	WIXELA INHUB AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496433010	WIXELA INHUB AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496439010	WIXELA INHUB AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496455010	WIXELA INHUB AER 100/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496461010	WIXELA INHUB AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496476010	WIXELA INHUB AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496482010	WIXELA INHUB AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496498010	WIXELA INHUB AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496504010	WIXELA INHUB AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496520010	WIXELA INHUB AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496526010	WIXELA INHUB AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496542010	WIXELA INHUB AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496548010	WIXELA INHUB AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496564010	WIXELA INHUB AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496570010	WIXELA INHUB AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496586010	WIXELA INHUB AER 250/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496592010	WIXELA INHUB AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496609010	WIXELA INHUB AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496615010	WIXELA INHUB AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496630010	WIXELA INHUB AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS

<u>Date of Service</u> <u>(Fill Date)</u>	<u>RxClaim Claim #</u>	<u>Drug Label Name</u>	<u>Claim Status</u>	<u>Local Msg</u> <u>(Custom Message)</u>
02/27/2019	190644496636010	WIXELA INHUB AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496652010	WIXELA INHUB AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496658010	WIXELA INHUB AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496674010	WIXELA INHUB AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496680010	WIXELA INHUB AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496697010	WIXELA INHUB AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496703010	WIXELA INHUB AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS
02/27/2019	190644496719010	WIXELA INHUB AER 500/50	R	DISPENSE BRAND - ADVAIR DISKUS